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HEALTH CARE FINANCING ADMINISTRATION'S MANAGEMENT OF MEDICAL LABORATORIES

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT OF GOVERNMENT MANAGEMENT

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

MARCH 23, 24, 1988

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HEALTH CARE FINANCING ADMINISTRATION'S MANAGEMENT OF MEDICAL LABORATORIES

WEDNESDAY, MARCH 23, 1988

U.S. SENATE,
SUBCOMMITTEE ON OVERSIGHT OF
GOVERNMENT MANAGEMENT,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:37 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Carl Levin, Chairman of the Subcommittee, presiding.

Present: Senators Levin, Cohen, and Heinz.

Staff present: Linda J. Gustitus, Staff Director and Chief Counsel; Allison C. Giles, Professional Staff Member; Mary Berry Gerwin, Minority Staff Director and Chief Counsel; Kim Corthell, Professional Staff Member; Sharon Ward, Professional Staff Member; Frankie de Vergie, Chief Clerk; Donna T. Omori, Intern; and Tania Chadbourne, Intern.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. The Subcommittee will come to order.

This morning the Subcommittee opens its hearings on Federal management of medical laboratories, in particular the extent to which the Health Care Financing Administration, or HCFA, is carrying out its responsibilities in this area. A number of news stories over the past months have jolted public confidence in even some routine medical tests upon which we regularly rely. These tests range from those that tell us whether or not we have strep throat to whether or not we have cancer. Our course of treatment and our lifestyle are directly dependent upon the results we receive from our medical tests.

If those tests are wrong, and we are unsuspecting of such error, we can be in the situation where we will either think we are ill when we are not, or thinking we are well, we could deny ourselves the medical treatment necessary to treat the actual but undiscovered illness. As our first two witnesses will so dramatically demonstrate, these tests upon which we routinely rely have life or death consequences.

These two days of hearings are part of the Subcommittee's investigation which has been conducted at the request of our ranking Republican, Senator William Cohen. His staff has done the bulk of the work in preparing for these hearings, and it is his interest in and commitment to this issue that has brought it to the attention of the Subcommittee. I commend him and his staff for their initiative.

There are some 13,000 clinical laboratories in this country that are regulated by the Federal Government. About 60 percent of these are hospital labs, about 40 percent are what we call independent labs. There are a large number of labs that are not regulated by the Federal Government, the vast majority of which—some 80,000 to 100,000—are in physicians' offices.

The labs that are federally regulated have been mandated to be so by law, either because they participate in the Medicare program or because they engage in interstate work. Those participating in the Medicare program are subject to regulations issued pursuant to the Medicare provisions of the Social Security Act; those engaged in interstate work are subject to regulations issued pursuant to the Clinical Laboratories Improvement Act of 1967, or CLIA. Some 1,200 labs are subject to regulation under both statutes, and that makes life interesting because the regulatory schemes—as the Federal Government, I am afraid, is wont to do—are somewhat, and I think unjustifiably so, different. In fact, HCFA has three different sets of regulations for medical laboratories: one for CLIA labs, one for Medicare hospitals, and one for Medicare independent labs. HCFA itself has now recognized that there is little or no justification for these differences.

Congress has permitted by law non-Government associations to substitute for the Federal regulatory process. We allow both hospital and independent labs, as appropriate, to be regulated by the Joint Commission on the Accreditation of Health Care Organizations, which we call the Joint Commission for short, the American Osteopathic Association, or the AOA, or the College of American Pathologists, or CAP. For those labs not regulated by these groups, we allow HCFA to use the State agencies to regulate the remainder of the labs under HCFA's jurisdiction. We thus have an entire system of regulation that is a step removed from the responsible agency regulator. Our hearings over the next two days will examine just how effective that system is.

Moreover, one of the most effective methods for determining accuracy and competency in laboratory work—proficiency testing—appears to be inadequately pursued, and we need to look at just how we can beef up that part of our regulatory program.

Some of the statistics that we have heard about in the press are shocking: that 20 to 40 percent of all Pap smears are false negatives, that is, they erroneously suggest a non-cancerous state; that in a 1986 review conducted by the Centers for Disease Control 1 out of 6 labs performed unacceptably in bacteriology and mycology tests. Bacteriology includes the identification of strep and staph infections as well as salmonella; mycology involves the identification of molds and fungi.

But I want to caution us all to remember, as we hear the bad news, that the vast majority of lab results are accurate and the advances in medicine which help us identify diseases and their causes at an early stage are of great benefit to us all. The goal of these hearings is to try to ensure that the Federal Government is doing everything it can and should to make laboratory testing of the highest quality and reliability possible.

I also want to point out that another goal of this hearing is to educate us as consumers, so that we do not blindly accept what we were told about our laboratory results. We need to be informed about our medical problems and conditions and pay attention to the fact that no system is or can be perfect. We should not blindly rely on test results just because they come tagged with the name "laboratory." We should question our doctors and hospitals about their choices of labs and their knowledge of the quality of the labs' performance. Our increased awareness will assist the medical profession and the Federal Government in addressing the problem.

We have a full plate—indeed, a full platter—of witnesses for these first two days of hearings. I look forward to their testimony as we probe the various aspects of this issue.

Now I call upon the ranking Republican of this Subcommittee and, again, the person whose initiative has brought us to this point. With the gratitude of all of us, Senator Bill Cohen.

OPENING STATEMENT OF SENATOR COHEN

Senator COHEN. Thank you very much, Mr. Chairman, and I appreciate your kind remarks and also how willing you were to schedule these two very important days of hearings.

Mr. Chairman, as you have indicated, millions of Americans routinely undergo lab tests to determine the source of their medical symptoms. Whether it is a simple throat culture taken in the family doctor's office or a test to determine whether a patient is infected with AIDS, lab tests are an integral part of health care. Last year alone, over 3.1 billion laboratory tests were performed in the United States. Lab testing has become a very large industry and a costly part of this Nation's health care. Last year alone, for example, over $20 billion was spent for lab tests, with the Federal Government picking up the tab for about 40 percent of this amount through Medicare and Medicaid payments.

As the Chairman has indicated, most patients never doubt the accuracy of their lab tests and may, indeed, believe that such tests are infallible. Yet faulty tests can and do occur. In some cases, a faulty test result can mean weeks of unnecessary treatment with the financial costs and emotional and physical strain associated with that treatment. This certainly was the case for Harry Turner, who was a 65-year-old man in Virginia who faced the prospect of a lifetime on kidney dialysis based on the results of four lab tests; four lab tests that led to numerous doctor's visits, more tests, unexpected medical bills, and months of fear and anguish—all of which, it turned out, were unnecessary because the lab tests were wrong.

Even worse, faulty lab test results can mean that a life-threatening condition in the patient goes undetected and can bring—as we will hear this morning in very compelling testimony—tragic consequences for the patient and his or her family. This was certainly all too true for Robert Johnson and Kathy and David Astor, who are going to be our first witnesses this morning.

As the Chairman has indicated, lab tests are never going to be 100 percent accurate. Any process, whether it involves individuals performing tests manually or lab tests performed by machines, is going to involve some measure of error. Over the past year, there has been an increasing concern over the level of accuracy—or perhaps I should say inaccuracy—of some common tests that are widely performed in this country.

Experts, the media, and workers in labs, for example, have expressed serious concerns over the accuracy of the Pap smear testing that is so critical to the early detection of cervical cancer in women, a disease that spreads rapidly and accounts for 7,000 deaths annually in this country. As we are going to hear in testimony today, the profit motive appears to have taken precedence over quality in some labs reviewing Pap smears. Practices such as piecemeal pay for reading Pap smears, average workloads exceeding two to three times the maximum limits recommended by professional societies, lab workers analyzing slides with little or no supervision, and labs not rejecting inadequate Pap smear samples from doctors for fear of losing business are severely jeopardizing accuracy in Pap smears and are contributing to the nationwide false negative rate of 20 to 40 percent that the Chairman has indicated.

The accuracy of other tests has also come into question. Recent reports have urged labs to improve the precision of their cholesterol testing, with one report concluding that the current status of cholesterol testing in the United States is "a situation that may handicap the national program to control heart disease." And, while hotly contested, it has been charged that some labs perform AIDS testing poorly, bringing about a high rate of false positive results.

It is in response to these concerns that the Subcommittee began an investigation of whether the Federal Government is doing enough to ensure quality in tests that are being performed by labs. Right now, the Federal Government has a very large stake in lab regulation. It has the responsibility to regulate, and to ensure quality practices, in approximately 13,000 labs, including both hospital and independent labs. The Congress has established two statutory schemes for Federal lab regulation, and the Chairman has outlined them: the so-called CLIA law as well as that performed under Medicare—all of which is supposed to be administered by HCFA.

The Subcommittee's investigation has identified major problems with the current Federal regulation of labs, some of which have a direct, adverse effect on lab quality. The current regulatory scheme is an uneven one, with multiple types and levels of enforcement. Different standards and enforcement mechanisms exist for labs operating across State lines and for those that are Medicare-reimbursed. In some cases, labs can be terminated under one program while continuing to perform the same tests and be reimbursed in another Federal program. We have found that there is a wide difference in the States' inspection and enforcement practices under Medicare itself.

Also troubling is the fact that the Federal Government does not have a national system on which it can decide whether to flunk or pass a lab for its performance of a particular test. In many cases the Government now lacks the tools it needs to take action against labs that do perform poorly on lab tests. Additionally, Congress has given over the responsibility to inspect and grade labs to private sector organizations that do not consider themselves to be regulatory or enforcement bodies. At these hearings we are going to consider the effect of these issues on quality, as well as overall performance of the Health Care Financing Administration in enforcing quality standards in labs.

Mr. Chairman, another major issue that has to be addressed at these hearings is the large number of labs that are unregulated by the Federal Government. Labs that operate totally within one State and that perform no Medicare work are not subject to Federal regulation. Neither are physician office labs, which have increased dramatically over the past decade. Estimates are that as many as 190,000 physicians may be performing some type of clinical tests in their own offices with the number of solo and group practices conducting tests in their own offices growing by an estimate 16 percent each year. Although a substantial percentage of tests being reimbursed by Medicare may be performed in these facilities, the Federal Government does not inspect or impose quality standards on these office labs. Today we are going to hear testimony on problems that can exist in these unregulated labs and opinions on what should be done to ensure quality results in lab testing, wherever it is performed.

During the course of its investigation, the Subcommittee has heard many cases of lab tests that went wrong, resulting in human tragedy or hardship. As the Chairman has pointed out, however, we have seen quality practices and performance throughout much of the lab industry itself. But vigilant and effective oversight of these procedures and performance by the Federal Government is necessary to ensure that the patient and the Government are getting the most for their money from lab tests that they do purchase. If the Federal Government is not doing enough, much more than simply money is at stake, and a great deal of money is at stake. As the Chairman has indicated, all too often what is at stake are the lives of the people who are submitting themselves to these tests.

Mr. Chairman, before we begin the testimony, I would like to pay particular thanks and gratitude to Mary Gerwin and Kim Corthell, of my staff, who were ably assisted by Sharon Ward from the GAO. These young women have been really the impetus behind the hearings, doing the investigative work. They have brought great intelligence and passion, I might add, to the subject matter. So I want to thank them for all of their hard work in making these hearings possible.

Senator LEVIN. Next let me call on Senator Heinz, who is a Senate leader on a whole host of issues, including health, aging, Social Security, Medicare issues, and many other very critical matters to us. Senator Heinz.

OPENING STATEMENT OF SENATOR HEINZ

Senator HEINZ. Mr. Chairman, I thank you. You are very generous. I think the generosity that you have shown in holding this hearing needs to be emphasized again.

I commend you on responding so quickly to Senator Cohen's and his staff's initiative. It speaks very well for you, Mr. Chairman, as well as the Committee for not being afraid to tackle—more than willing, I should say, to tackle any idea and problem regardless of who brings it to you. I know from my own personal experience that this has always been the case with you, and I think it always will be.

I also commend Senator Cohen, who I have had the privilege of working with on the Committee on Aging and who has had a great interest in health matters, as demonstrated by not only his voting record, but in his pursuit of so many health care issues, on having structured the hearing. I can remember, back in 1978 when we were first on this Committee together, his probing inquiry of Administration witnesses on long-term care and why we were not seeing progress.

When he commends his staff, let me tell you I know how much staff work it takes to put on a good oversight and investigatory hearing. Senator Cohen participated in many hearings that we had in the Senate Committee on Aging that I was privileged to chair. So when he commends his staff, indeed, they do deserve it.

I would like to make four brief observations, Mr. Chairman. The first is that poor quality in clinical lab tests, unlike other sectors of our health care system, has a very visible outcome, such as wrong diagnoses and misdiagnoses that dramatically change the course of patient treatment and can change the course of an individual's life.

Secondly, when we are dealing with problems in testing that fail to pick up preventable cases of, for example, cervical cancer or that erroneously diagnosed persons as having AIDS or other terminal illnesses, we have entered into a realm of public responsibility where preventable error becomes intolerable because of the profound medical and moral consequences.

Where some might settle for an achievable accuracy rate of 99 percent, I would look at the remaining one percent which would be, of the 3.1 billion tests, 31 million tests. That is one percent who would get wrong test results and whose treatment and, in some cases, life decisions are misdirected as a consequence.

Third, there is compelling evidence that the Health Care Financing Administration's (HCFA's) management of both Medicare reimbursed and interstate labs has been, at best, poor and that we in Congress have ourselves only begun to address the range of legislative reforms needed to make sure that lab tests, independent of setting, are of the highest level of quality and accuracy possible.

I would point out that Congress has started to take a few moves. Last year, the Finance Committee adopted reforms as part of OBRA in 1987 based on legislation that I offered to extend the range of sanctions and civil penalties available to HCFA in enforcing existing standards. One question that I intend to raise is what progress HCFA has made in implementing this new authority and whether barriers exist that might prevent HCFA from taking full advantage of that authority.

I do think that sanctioning authority is only a small part of the answer because, from my own review of the evidence available to which I anticipate these hearings will add measurably, it seems to me that nothing short of an overhaul on how standards are set, how data are collected, how all labs across settings are monitored, and how, if at all, we apply deemed status for clinical labs will do the trick.

The Administration will undoubtedly tell us that their long-awaited April regulations are going to address all of these problems. I would certainly like that to be true. I hope it is true, and I look forward to hearing what they have to say tomorrow.

I will simply say, Mr. Chairman, on one other matter, that you have been very kind to invite a witness, Mrs. Josephine Bartola from Pennsylvania, who is going to describe an innovative program for monitoring clinical labs across all settings. It is a very interesting experience, and it is my hope that I will still be here at roughly 11:30 when she is able to testify. But I have two other hearings, as often happens, that I may have to go to, and I have a statement I have to make on the floor before noon. So I cannot guarantee Mrs. Bartōla that I will be here when she testifies, but I certainly will try.

Mr. Chairman, again, I commend you. I thank you and Senator Cohen for what I think will prove to be a series of very important, indeed historic, hearings.

Senator Levin. Thank you, Senator Heinz.

Our first panel is Robert Johnson of Venice, Florida, and Kathy Astor, Sunnyside, New York. Ms. Astor, Mr. Johnson, can you come forward, please?

Ms. Astor, if you could sit right there, that would be fine. Thank you.

Mr. Johnson, if you could sit next to Ms. Astor.

Apparently, Mr. Johnson, you are first on our list, and we will call on you first. Perhaps you could also introduce the person who is with you.

TESTIMONY OF ROBERT JOHNSON, VENICE, FL, ACCOMPANIED BY DANIEL SCHULTZ, ESQ.

Mr. Johnson. Good morning, Mr. Chairman and members of the Committee. My name is Bob Johnson. I am the husband of the decedent, Janice Johnson.

This is Daniel Schultz, who is my attorney.

Mr. Schultz. Good morning, Senator.

Mr. Johnson. I am probably going to give you a combination of some reading from the written testimony [1] and then some extemporaneous comments, mainly in the preservation of time, but also I have discovered that in speed-reading this, I probably occupy somewhere between 16 and 20 minutes. I think we can condense that to your benefit.

Senator Levin. That would be fine. Thank you.

Mr. Johnson. I quote, "It was 4:30 a.m. when cancer finally choked the last breath of life from Janice Johnson. She was 34 and a mother of two, and she died never knowing why her disease has been so unforgiving. An autopsy report called her abrupt decline 'quite unusual.' "

"Later, an important clue would be discovered. A hospital laboratory in Arlington, Virginia, has erroneously reported two successive Pap tests as non-cancerous. Undetected, the cancer spread rapidly through Mrs. Johnson's body."

Those were the opening two paragraphs as reported on the front page of the Wall Street Journal just over a year ago.

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[1] See p. 131.

I went to Jan's gravesite yesterday and visited her. I told her I was going to be coming here today to talk to you folks. And as irony would have it, as I am walking this morning to meet Dan, it just so happened that I walked by the restaurant where I was able to take her to from the hospital for a few hours, and we enjoyed our last meal together. Needless to say, that has put a little bit of a dampening on my ability to present because, once again, the emotions of what happened have really been aroused.

Let me just simply say that the entire problem with this cancer began with the birth of our second son. We did not know it, but after her delivery she had some unusual bleeding and perhaps warning signs that we just dismissed, thinking it was a problem with post-pregnancy. But after a couple of months, the bleeding subsided, and with the passage of having missed a couple of cycles, we came to the conclusion, quite frankly, that she was pregnant. She was going to go to the gynecologist to find out and reaffirm that, indeed, she was pregnant with a third child.

But, unfortunately, she passed a huge blood clot and resumed bleeding once again. This time she went to the gynecologist; now we are fearing that the joy has turned into the fear of having miscarried. And we got hit with a double whammy. That is, when she was advised that, upon physical examination—notice I say physical examination—that she had cervical cancer, which came as, needless to say, quite a shock to us because she had been having her regular Pap smears and being told that it was negative, which is certainly great news to hear. But, unfortunately, we did not realize that they had been misread at the time.

The conclusion we came to was that someone had basically screwed up. We did not know who or why, but we vowed that once she got better we were going to find out who was responsible and, frankly, put them out of business so this could not happen to anyone else. Unfortunately, Jan never had the opportunity to do so, and although I attempted by myself afterwards, I can tell you, for those that are still alive, it is business as usual. There has never been any public acknowledgment of any guilt or wrongdoing.

Janice Johnson was a very extraordinary lady. She was beautiful both inside and out, well educated, and very knowledgeable in the medical field. She was a former educator who came to Washington and joined the staff of a U.S. Congressman. Later, she became the chief lobbyist for one of the largest national medical associations. The point that I bring up here is that here you have a lady that was extremely knowledgeable in the field, and she even knew all the warning signs of cancer because there had been a history of cancer in the family, most of them having died very young from it. So with all this knowledge and firsthand experience and technical capabilities, she still did not know that she had contracted cancer.

I guess the question I would raise is: What about the average person in the street that has no knowledge at all? They are pretty much relying upon their gynecologists. I know most women dread going to the gynecologist. It is a dehumanizing experience to begin with. But when they come back and tell them that the slide is negative, that is certainly great joy. And they believe this in blind faith.

It is just incredible. I had no knowledge of the inner workings of the system, and the analogy that I use is that, you know, a builder is only as good as his subs. The question I raise is: Who is running the ship? We really thought that by having a fine gynecological team that all of his subcontractors were going to be of the same caliber, not realizing that this is not the case. In fact, I think most women would be quite surprised to find out that their physician likely cannot even read a slide. It really shatters your faith and confidence in the system.

Jan was the big loser because she lost her life, of course, but the human tragedy continues. It changed our lives forever. I had two very small children at the time that she contracted cancer, 15 months and 3 years old. They never knew their mother; she never knew them. They really have nothing to remember her by. There is a small box of photographs and some other memorabilia, and that is about it—except for the fact that on her gravesite I did write a poem, which I would like to read to you.

It is:

> Mother, Woman and Wife, by cancer early in life, her grace, love and style was ours but for a while, rode a rainbow to heaven on Feb. 23, never forgotten by her two boys and me. Signed . . . her husband.

In my mind, this was not what has been labeled as a wrongful death. In my opinion, it is borderline criminal. I ofttimes ask myself the same questions over and over. How many more Janice Johnsons have been unnecessarily killed due to inaccurate lab results during the last 85 months since her death due to either incompetence, fatigue or lack of training? Why is there no self-regulation by the medical profession itself? Or why not at least some uniform Government regulations? How could this possibly have happened? Who is responsible?

In the beginning, I thought that Jan's situation was purely an isolated incident, but I am convinced that you will discover that that was only the tip of the iceberg. It is debilitating to deal with cancer, but to find out that one likely could have been cured, had early detection been there, is absolutely deplorable.

The question over lab procedures is not a new issue. It has been before the Congress before. But, unfortunately, nothing has happened due to the pressures of the medical lobby.

I am sure that the testimony that you will be hearing today will provide you with lots of statistics, but I simply want to mention in passing what has already been mentioned: This is big business, $20 billion a year, and I think it is an industry that is running rampant and unchecked by any controls—purely regulated by profit.

I find it unconscionable that some of the costs associated with this thing is 50-cent Pap slides, and the cost gets passed on to the patient for as high as $35. It does not matter what I paid for it. I do not even remember. But the point is the results I got were not even worth 50 cents because they were wrong.

Industry standards, I understand, recommend that 80 slides a day be read, and I have heard in some cases where as many as 200 slides a day have been read by technicians. In my own personal case, I further understand that it was upwards of in the 300 area. That is not screening, in my mind. That is just running them through a factory.

Like an architect that puts seals on his plans after he reviews the work of his draftsmen, I ask the question also: Where was the head of the lab? How many slides did he review and sign off on? How many slides did he not review and sign off on? Again, how many slides did the technician read that day?

The most important question I would ask is, really: How many slides were misread? And how many people died or are dying today and do not even know it?

These are a few of the questions that I continuously ask myself, and I think these are the questions that need to be addressed and dealt with.

Again, what happened to my wife was very avoidable, and my deep-rooted anger is only overshadowed by the pain that I feel over her loss. This profession has had the opportunity to regulate itself and, in my judgment, has failed to do so. I usually do not come down on the side of additional Government regulation, but when an industry fails to respond and the public is at risk, I think it is time to mandate some kind of uniform Federal standards to protect the public.

I do not believe that a State-by-State approach will solve the problem because of the weak-link principle. It is merely going to produce shoddy labs in States that have weak or no regulation at all. To me, it is not the solution to the problem. Ensuring accurate test results, to the extent that it is economically feasible, is the solution.

In conclusion, it has been said, "Everyone is famous for about 15 minutes." I do not know how many other Janice Johnsons there are out there, either dead or dying because of inaccurate lab results. But hopefully, I have spoken on their behalf.

I sincerely hope that Janice and all the other victims who could not be here today will feel famous for a lot longer than 15 minutes. I urge that you take decisive, corrective action on this issue and do not succumb again to the medical lobby.

If Janice's story can save but one life, then I can look my children in the eyes and tell them when they are old enough to understand that their mother did not die in vain. She, with the help of Congress, changed the laws to save thousands of lives.

Thank you.

Senator LEVIN. Mr. Johnson, we thank you for your willingness to step forward and to share your private grief with us publicly. It is our hope and our prayer that, indeed, some major good will come from your suffering and that of your wife. That is our obligation.

Mr. SCHULTZ. Mr. Chairman, might I have just two minutes in order to explain why, from Mr. Johnson's standpoint, this case is a wonderful example for you to begin with at your hearings.

Senator LEVIN. Sure. Proceed.

Senator COHEN. Please identify yourself again, for the record.

Mr. SCHULTZ. My name is Daniel Schultz, and I am Mr. Johnson's attorney and represented the Johnson family in the medical negligence claims that arose out of her death.

The laboratory involved was not a Beltway laboratory, unnamed organization. It was a major hospital in the Washington metropolitan area, Northern Virginia Doctors' Hospital. It is a major medical supplier in a major metropolitan area. It is some place that you would expect would be regulated, would have standards to be applied. If there is going to be Federal regulation governing, this hospital should have been under its auspices.

It is an example in a setting of a misreading that is one of the most sinister situations possible because it is cervical cancer, Pap smears in a reading that is made on a preventive basis without symptomatology in order to have early detection of cervical cancer before it becomes invasive. There is no backup for diagnostic help where you are presenting with somebody, a patient that is sick and the doctor, the treating doctor is attempting to find out why.

If a lab comes back and misreports in that setting, the doctor is going to keep looking. It may result in a delay, but he is going to keep looking until he gets an answer to the problem of why this person is sick. Pap smears are not in that category. They are prophylactic for early detection. And if you miss it, you can end up with death, as happened with Janice Johnson.

It is a classic example because Janice Johnson's Pap smears were misread two years in a row; in 1978 misread, in 1979 misread. Her diagnosis of cervical cancer happened in 1980. They were reported by Northern Virginia Doctors' Hospital as Class II's, no cancer, no malignancy. In 1978, the proper classification admitted by the head of the pathology laboratory during the course of the litigation, the proper classification, Class IV, strongly suspicious of malignancy. And anything from a Class III up, it requires follow-up. That is a given. It was reported as Class II.

In 1979, admitted by the head of the pathology laboratory when he finally looked at the slides—Class IV again, strongly suspicious of malignancy. And the fact was, Janice Johnson had cervical cancer in 1978 and 1979.

The result of the delay, because she did not go in, and it was not found on physical until the symptomatology started, was it had become invasive by the time the diagnosis was made. Invasive—it had gone beyond the cervix, it had invaded the lymph nodes. It was in her system.

The surgical treatment that followed and the nonsurgical treatment that followed was completely unsuccessful. It had gone beyond the point of being saveable, and she was dead within one year after suffering a horrible year, both her and her family.

Why is this a perfect example? Because there were absolutely no quality controls in place for reading Pap smears at this hospital—none. There was no spot-checking of Class Is and IIs by a pathologist. There was no supervision of the person who was reading these slides. There were no written protocols. There were no written standards. There was nothing there.

Why is this a classic case? The person who was reading twenty thousand Pap smear slides per year for this hospital from 1975 on was the only person doing it, and this person had flunked their pathology boards in 1975, had flunked their pathology boards in 1977, and had flunked the clinical side of the pathology boards in 1979.

This person was totally unsupervised and was the only person reading these slides.

Lastly, why is it an ideal case? Because of the volume that was being presented. The person who was doing this was a house physician on staff at Northern Virginia Hospital in a full-time position.

She was reading the Pap smears as an extra job, a part-time extra job on top of her full-time duties. She was putting in extraordinary amounts of hours during the day in order to accomplish these two functions, and she was being presented with what she estimated to be twenty thousand slides a year. She was working approximately five hours a day, reading Pap smears. Any way you cut those figures, it comes down to an average of three and one-half minutes per set of Pap smear slides, which are two slides—way below standards both in terms of quantity, in terms of minutes to be allocated to it.

Lastly, why is this an ideal case? Because while an attorney can successfully represent an individual victim in a medical negligence setting such as this, it is extremely difficult to go beyond that individual case.

These smears and the error in misreading, a gross error, were discovered as soon as a diagnosis was made in Janice Johnson's case in 1980. They went back and looked at the smears, and they realized this mistake had been made. Nobody told the Johnson family. The private physician, the gynecologists were informed; the laboratory knew; the Johnson family did not know.

And during the course of the litigation, there was never any indication that either the gynecologists who had been sending all their Pap smears to this laboratory, or the laboratory, took any steps to determine whether or not, in how many of the other twenty thousand women who had their Pap smear slides going through this place every year were at risk and were waiting for their error to be found out—no follow-up.

It is only with some effective regulation that these quality control standards are going to be required, that there is going to be improved quality control, that this type of practice is not going to happen. And the more you move into private laboratories and private physicians and move even out of the hospital setting, the greater the problem.

That is why I think this is an ideal case.

And lastly, it is because this case is over. What I have said to you are facts in the record. And Northern Virginia Doctors Hospital has an opportunity to respond, and I understand has some thirty days to give a response to this, to explain why they were operating their lab the way they were and explain what happened when they found out about their mistakes and how this was handled and explain to this Committee why it found itself in a situation where it was running its laboratories the way I have described for the years involved.

Thank you very much.

Senator LEVIN. Thank you, Mr. Schultz.

Mr. Johnson, just a few questions for you, and then I will go to Mrs. Astor.

Mr. JOHNSON. Yes, sir.

Senator LEVIN. How were you told or how did you find out about the mistake—mistakes, I should say?

Mr. JOHNSON. As far as when Jan came home and announced that she had it or——

Senator LEVIN. How did you find out that the tests were erroneous? Who told you when and under what circumstances?

Mr. JOHNSON. This is what Daniel found out through investigation after her death.

Senator LEVIN. In other words, you knew nothing about the error in these tests until after your wife's death?

Mr. JOHNSON. That is correct. She never knew.

Senator LEVIN. Do you know or does your lawyer, Mr. Schultz, know anything about the accreditation of this lab by the Joint Commission? Do you know whether they had been accredited?

Mr. SCHULTZ. It is my belief that they were, but I do not know that for sure. It seems clear that they should have been subject to regulation and accreditation, but I cannot say for sure that they were.

Senator LEVIN. Have you learned anything about the time-table? Was this lab, for instance, reviewed prior to the tests in question?

Mr. SCHULTZ. That information never was revealed during the course of the litigation.

Senator LEVIN. You do not know, you are not privy to that information?

Mr. SCHULTZ. I am not.

Senator LEVIN. And have we learned anything or have you learned anything more about that lab? For example, was it viewed by the Joint Commission as a troubled lab at any time?

Mr. SCHULTZ. Their designation or the results of evaluation, their status was never revealed during the course of the litigation, so I am not privy to it.

Senator LEVIN. All right.

Mr. SCHULTZ. I do know from the way they operated their lab that they were not in compliance with any type of standards that were in existence at the time or recommendations.

Senator LEVIN. And do you know whether any remedial action has been taken against the lab at any time, now that we know about these errors or for any other errors?

Mr. JOHNSON. I have no knowledge of that whatsoever.

Mr. SCHULTZ. None to our knowledge.

Senator LEVIN. And do you know if anything has been done in that laboratory to reduce the likelihood of error since these mistakes were discovered?

Mr. JOHNSON. I am sure I would be the last person to find out from them.

Senator LEVIN. Does your lawyer know?

Mr. SCHULTZ. It is one of the problems of individual litigation. You end up with curtailment of the information available and steps or changes taken post a particular event are not necessarily available to you. The answer is I know that the person that was reading the slides was let go by the hospital. But as far as what procedures they put into place afterwards or what steps, if any, they took to improve, we were not provided with that information.

Senator LEVIN. And the same person misread both slides, both sets of slides?

Mr. JOHNSON. That is correct, sir.

Senator LEVIN. Senator Cohen?

Senator COHEN. Just a couple questions, Mr. Johnson. I can certainly identify with what you have been saying here today. Long after we had set these hearings, I learned that a relative of mine had incurred a similar experience to that of your wife. She had her Pap smears misread for over a year, only to be told she actually had active cancer at this point, causing quite a bit of extensive surgery. I understand exactly what you have been saying.

If I could perhaps turn to your attorney, what was the hospital's response to the issue of the flunking the pathology boards by the person reading the Pap smears. Did you raise that as an issue in the course of the litigation?

Mr. SCHULTZ. Initially, they took the position of no liability, no substandard care, et cetera. During the course of the litigation, when we were able to take the deposition of the chief pathologist, Dr. Enos, of this laboratory, who had looked at the slides and secured his acknowledgement and his admission of their having been misread and that they did show cancer, the hospital then took the position that they were in fact misread, they acknowledged it and they took the position that it did not make any difference, that Janice Johnson's cancer would have killed her anyway, and that was the issue then that was left and was put in controversy by the hospital as they attempted to defend against the claim.

Senator COHEN. Was the issue of whether or not they had employed a person who had flunked the pathology boards in 1977 or 1979 raised during the course of litigation?

Mr. SCHULTZ. Yes, they took the position that because the person involved was a medical doctor, she had secured a medical degree from a school outside this country but was a medical doctor, that as a result she needed less supervision and they could place more reliance on her reading than a technician. What that overlooks is that a technician has special training in sitology, which is exactly what we are talking about with Pap smears, and that this person, while on one level looking better than a certified technician, cytologist, because she has a medical degree, in fact was not as qualified, particularly in light of her performance on her board exams.

Senator COHEN. Well, what you are saying is there was a person who got a medical degree outside of the country being employed to read the Pap smear slides, having flunked a test in 1975, 1977, and 1979, on three occasions prior to reading the test slide?

Mr. SCHULTZ. That is correct, and it was known by the laboratory and by the hospital. She was not—she did not have privileges to admit, if she was a house physician, and was there all during the period of time and was reading the Pap smears for extra dollars, making $5 to $6 an hour and doing it either before her regular duties at the hospital or for extra hours after her duties at the hospital.

Senator COHEN. Reading about 300 Pap smears a day?

Mr. SCHULTZ. It broke down to—her estimate was 20,000 a year, and she was spending five hours reading Pap smears, five hours a day. On another occasion, she—another way of looking at it, she said they range from 80 or maybe I think she said 60 up to 300 a day that would come in and she placed the average at 80 a day. Well, if you look at the reduced hours that she was working, not as a full-time person, either way you look at that, it comes out to between three and four minutes a day.

One of the problems again exemplified by individual claim representation is we have much difficulty getting the raw records because of medical privileges. We were not allowed to get the entire sequence of records for Pap smears in order to be able to do a more accurate count and we could not go beyond Janice Johnson's slides as far as how they were being evaluated or determine the extent and rate of failure. What we could say and what was so glaring about it is either this was a completely unusual situation, two consecutive years, two gross misreadings by the same technician, I mean she had a bad day one year and a year later she had another bad day, or this was something that was happening with regularity. That in turn raises the question that was always troublesome, and that is what happens to the other 20,000 people and why are there not steps being taken to remedy the problem and make sure that it does not exist and follow through.

Again, in an individual setting you cannot do that, you need the regulatory body and a system in place so that if you realize this is happening you can say to them, you want to keep your accreditation, you are going to have to do something about this, go back to your records and send out notices, look at these slides, let us do a sampling and find out if in fact this problem is a huge problem.

Mr. JOHNSON. If I might add a personal note on that, first what I find frightening about this entire situation is women are warned not to smoke or drink during their pregnancy. It is a fact that she was pregnant with the second child all through the cancerous state. That troubles me dearly. Plus strange things have been known to happen to slides, they happen to disappear, they break. We know of two misreadings. Okay. She may have been cancerous long before that, but because of the deterioration of the slide there was inconclusive evidence. She may have been cancerous with my first son. That frightens the dickens out of me.

The other thing I would like to mention is that is what makes this issue so important for the women. Please keep in mind that they are going to the gynecologist looking for good news stories, and when they hear the slide is negative, ooh, no problem, and that is their line of communication. It is frightening.

Senator COHEN. A couple of other points, again to your attorney. I think you indicated that they had no system of spot checks. Also, they had four categories. For category 1 and 2, there was no reason for alarm that would require a supervisor or another physician or pathologist to double-check the slide. So if it was only categorized as number 1 or 2, no overview, is that right?

Mr. SCHULTZ. That is correct, Senator Cohen.

Senator COHEN. Only when the slide was categorized 3 or 4 was there any supervision at all?

Mr. SCHULTZ. That is correct.

Senator COHEN. So, I think to use your analogy, Mr. Johnson, of a sort of factory assembly line process that keeps speeding up the belt, the slides keep going through faster and faster. They are just speeding up the belt and no one is checking at the first two levels. No one is taking a percentage, checking 10 percent of the slides that are being categorized as 1 or 2, is that right?

Mr. SCHULTZ. That is correct, Senator Cohen. If the person reading them concluded there was a 1 or 2, as in Janice Johnson's case, there was no set policy for review either for all of them or, say in class 2's, or for any spot checking, regular spot checking, 10 percent, 20 percent pull on them to make sure that they are being accurately reported. There was none of that.

The only thing that was pulled for the pathologist to look at by the person reading these slides were ones that were labeled by her as Class 3's or Class 4's, and those would be looked at before they would be reported as being malignant or suspicious of malignant.

Senator **Cohen**. I take it that, number one, there was no negligence, and, number two, if there was negligence, it was too late by the time her slides were read, even if negligently, to make a difference?

Mr. **Schultz**. That is correct.

Mr. **Johnson**. Senator, one last comment. This has not come out in testimony or any of the public presentations that I have made. After her delivery, Janice had sent or requested her slides be sent back for rereading, and the report she got back from the gynecologist was that it was simply Class 2, I guess it was, minor inflammation and, again, nothing to worry about.

Senator **Cohen**. Thank you very much, Mr. Johnson.

Senator **Levin**. Just on that point, was that a third reading, a third misreading?

Mr. **Johnson**. You can classify it as that, yes, because she requested—she was suspicious, I mean she did not tell me a whole bunch, but she was troubled inside. She was suspicious and asked that it be sent back for rereading.

Senator **Levin**. And were they reread?

Mr. **Johnson**. I do not know.

Senator **Levin**. Did she believe they were——

Mr. **Johnson**. I think she believed that they were reread.

Senator **Levin**. So there may have been a third rereading or there was at least a belief that there was a second reading of that one set of slides?

Mr. **Schultz**. Yes, Senator, there was the belief.

Senator **Levin**. The American Society of Cytotechnology has set a standard of 80 slides over a 24-hour period. In other words, 80 slides per day would be the maximum that would be read. What you are saying, Mr. Schultz—and I think Mr. Johnson may have commented on this—is that this particular technician or doctor read about 80 slides on the average in a five-hour day, which was on top of her regular day. Is that about right?

Mr. **Schultz**. That is correct.

Senator **Levin**. So if that 80 standard is about right for 8 hours, she was almost doubling that standard if she did it in 5 hours. And the 5 hours that she put in was on top of her regular 8-hour day, correct?

Mr. **Schultz**. That is correct, Senator.

Senator **Levin**. Okay. Just one question about the gynecologist. Did your gynecologist learn about the error prior to your wife's death?

Mr. **Johnson**. I would have to defer to Dan. I was probably brain-dead there for a good two years.

Mr. **Schultz**. Yes, according to the testimony during the course of litigation, the gynecologist had learned of the error shortly after the diagnosis had been made in 1980. Janice Johnson died in February 1981, approximately a year after diagnosis, so the answer, Senator, is yes, they had learned.

Senator LEVIN. But your gynecologist then did not share that information with the family, is that accurate?

Mr. SCHULTZ. That is correct.

Senator LEVIN. And do you have any comment on that?

Senator COHEN. Was he joined as a defendant?

Mr. SCHULTZ. Yes, the gynecologists were party-defendants to the lawsuit. It is my view, Senator, that a failure to share this information with the patient technically violates the medical ethics. That is important information relevant to the patient's health and I believe a fair reading of the medical ethics requires a sharing of this information. I think it is fairly obvious why that information ends up not being shared when something like this occurs when it is in fact not disclosed.

Senator COHEN. It is ironic that we have recall of defective cars and send out notices and impose regulations upon the manufacturers of automobiles for a defective starter or defective switch on a gas pedal, but do not have an effective policy of recall here.

Mr. SCHULTZ. Well, you can imagine what the notice would have been to the patient population for the gynecologists involved. After they found out what had happened and with some inquiries, such as finding out who is reading these Pap smears and finding out that the boards had been flunked two years in a row, the notice to the patients who had had Pap smears processed through that office would have read something like,

> Dear Patient: This is to advise you that your Pap smear that was read last year and the year before was read by someone who we have now found out had flunked their boards two times and is someone who has now misread, we know has misread a Pap smear two years in a row, you may want to have another Pap smear.

That is the kind of notice that would have to have gone out, and obviously it is disturbing.

Senator LEVIN. Do we know whether the hospital conducted any review of the Pap smears that were read by that particular person following your wife's death or the awareness of what happened here? Do we know if they have done any of that?

Mr. SCHULTZ. We were not privy to that information.

Senator LEVIN. You are not able——

Mr. JOHNSON. What I was going to say is that is why I used the analogy that it may have been the lab technician that represented the bullet that killed Janice, but everyone helped hold the gun and pulled the trigger. There is some breakdown in the system that needs correction all the way through.

Senator LEVIN. Thank you both.

Now we are going to turn to Kathy Astor. Mrs. Astor, we very much appreciate your willingness also to make your situation and your story public, in the hope that it is going to help perhaps millions of other people avoid the same kind of problem that you and your child have suffered.

TESTIMONY OF KATHY K. ASTOR, SUNNYSIDE, NY

Ms. ASTOR. Thank you. I hope so.

First, I would like to introduce the person on my right; this is my husband, David Astor. I want to read my written statement and make some suggestions afterwards for improvements in laboratory testing, and if there are any other questions I will be glad to answer them.

I would like to say, first of all, that I feel that Robert Johnson and I have something in common. He lost a wife that he loved very dearly because of a laboratory error, and my husband and I are going to lose our daughter, who is 21 months old now, because of a laboratory error.

Our difficulties began in October of 1985, when I found out I was pregnant. Since both my husband and I are of Eastern European Jewish background, my then-obstetrician advised my husband, Dave, to have a blood test to see if he was a carrier for Tay-Sachs disease, a fatal and incurable progressive neurological disorder most commonly found among people of our background.

Tay-Sachs babies live an average of 2.5 to 5 years. One in every 30 Jewish adults is a carrier, and there is a 1 in 4 chance with every pregnancy in a marriage where both parents are carriers of having a Tay-Sachs child. Because both parents have to be carriers, my doctor did not advise me to get tested. My husband's blood was drawn in the obstetrician's office and analyzed at Kingsbrook Jewish Medical Center, in Brooklyn. The results showed that Dave was not a carrier. Thus reassured, we went ahead with the pregnancy.

Our daughter Abigail Laura was born on June 10, 1986. Her physical development progressed normally for the first six months, although in retrospect there was a general unresponsiveness about her that we were not fully aware of at the time.

After the first six months, we became increasingly concerned about her physical development. She was making no progress toward sitting up by herself or crawling, and she could hold no toy other than a rattle. Her pediatrician kept telling us that she was fine and making normal progress, but by the time she was 11 months old we were thoroughly worried. On May 4, 1987, we took her to another pediatrician who thought there was something wrong and advised us to take her to a neurologist, which we did the same day. Among other things, the neurologist looked in her eyes and saw two highly indicative cherry-red spots. His diagnosis—Tay-Sachs disease.

We were devastated, of course, but also bewildered, given the results of Dave's carrier screening test. The doctor was bewildered, too. He felt Abigail might have a variant of Tay-Sachs disease that would not have been detected by Dave's carrier screening test, and for the next month after Abigail's initial diagnosis, Abigail, Dave, and I were given a battery of tests at Columbia-Presbyterian Hospital in Manhattan to determine what variant might be involved.

On June 5, 1987, I contacted the director of the genetics laboratory at Columbia-Presbyterian to get the results of some tests. He seemed flustered and unwilling to talk, but finally told me that he and the neurologist had both talked with Dr. Larry Schneck, director of the laboratory at Kingsbrook Jewish Medical Center.

The neurologist, who was the first to speak with Dr. Schneck, told him that he had diagnosed Tay-Sachs in a baby whose father had been screened and found not to be a carrier by Kingsbrook. Dr. Schneck went back to the notebook kept by the lab technician who had performed the test. There he discovered that, although the test itself had been done correctly, in calculating the results the technician had made a mathematical error that made it look as though my husband was not a carrier, when, in fact, he was. Kingsbrook did not have a policy of double-checking lab results, so nobody discovered the error.

Dr. Schneck was asked if he wished to tell us about the error, and/or to speak to us in general. He replied, according to what the lab director at Columbia-Presbyterian told me, that he did not "believe that was obligatory," but that he would be willing to speak to us if we wanted to contact him.

Naturally, we felt that such a communication should be initiated by Dr. Schneck. So it was left to the neurologist and the doctor at Columbia-Presbyterian, neither of whom was responsible for the error, to tell us about it. In addition, we were told that Dr. Schneck had initially considered firing the lab technician who made the error, but had decided against it, because, after all, the harm had already been done. Since that time, we have not received a single letter or phone call from Dr. Schneck or anyone else at Kingsbrook. No explanation, apology, or help has ever been offered, although we have written to Dr. Schneck, sent him media items about us, and he has also been told by a doctor on the Scientific Advisory Committee of the National Association for Tay-Sachs and Allied Diseases that we are upset by his silence.

Except for a heightened startle response—she would jump at any sudden noise—Abigail's deterioration did not become readily apparent until September. At that time she began having seizures, and in late September had to be hospitalized for three days because of several major seizures in which she stopped breathing, turned blue, and threw up. She was put on antiseizure medication, which almost completely eliminated the most severe seizures, but not the minor ones.

Following her hospitalization in September, Abigail began to deteriorate rapidly. She went blind, stopped laughing, smiling, and even crying, and lost the ability to roll over, grasp rattles, and hold her head up. Since early October, Abigail has been almost completely paralyzed. Except for minor arm and leg movement, she is totally unable to move and she has no head or neck control. In early October, we started at-home nursing care for Abigail during our working hours, which has kept her as comfortable as possible. In early December, Abigail's swallowing ability deteriorated to the point where we had to begin tube feeding her. Since she cannot swallow, Abigail gets very congested. And since she has no muscle control, she cannot have bowel movements on her own. Abigail's regression has been closely monitored from the beginning by a team of doctors at Mt. Sinai Hospital in Manhattan, whose warmth, concern, and efficiency has helped keep us sane.

Obviously, all of this has affected my husband and me emotionally on a very deep level. In late August, we started seeing a psychotherapist once a week, both to help us deal with our grief and to help us keep our relationship together. This therapy has helped us a lot. In mid-December, I transferred to a less-pressured job in another department of my company, at a pay cut of $5,000 a year. Also, since October I have had two miscarriages caused by stress.

In June, Dave and I began looking for a lawyer to bring suit against Kingsbrook. They all turned us down, because in New York State the law does not allow damages for pain and suffering in wrongful life cases. We were told we could only collect for extraordinary medical expenses not covered by insurance, and since my husband and I are both well insured through our jobs, the financial reward was not worth it for a lawyer. However, in early July we found a lawyer who agreed to take our case.

Since a lawsuit is not likely to hurt Kingsbrook, we have been seeking as much media publicity as possible. If Kingsbrook's name and their careless laboratory procedures are publicized enough, maybe they will think twice about being so careless again. Perhaps, too, we can help other people avoid the same kind of tragedy. We have been mentioned in an Omni magazine article, have had a letter published in Dear Abby,[1] and an article published in New York Newsday.[2] A New York State Department of Health investigation of Kingsbrook was triggered as a result of the Dear Abby letter. The report, which is now available from the New York State Department of Health, confirmed that the error had been made. In addition, our case is one of several to be described in the June issue of Ladies Home Journal.

Most recently, we have made a decision to hospitalize Abigail permanently. Abigail is still at home as of now, but we have begun the admission process. We have found a wonderful facility in another part of Queens, where we live, where Abigail will receive the skilled and constant care she deserves, and that we no longer have the emotional or physical stamina to give her.

That is the end of my prepared statement. I have been doing a lot of thinking and my husband has been doing a lot of thinking about what labs could do and what Kingsbrook could have done specifically to prevent an error like this from happening.

One thing is obvious, of course, they could have double-checked the lab results. This lab test was done by hand. We were told that most of the Tay-Sachs screening at Kingsbrook is done by machine, but for some reason this test was done by hand and yet it was still not checked and the error was a very simple one, something like 50 minus 25, and the technician got the wrong figure and no one checked the results.

We feel that all lab tests, especially if they are tests for a condition which is life-threatening, as this one is, should be double-checked. Also, in Tay-Sachs screening in particular, both parents should be tested because both parents have to be carriers. In our case, Dave was tested and found not to be a carrier. I was not tested because we had faith in the results of Dave's test. We did not know that I was also a carrier.

There are hospitals, and Mt. Sinai is one of them, which do Tay-Sachs screening and which refuse to test people unless they come in as couples. They will not test individuals, and if Kingsbrook had followed this procedure this would probably have never happened.

We also feel that laboratories should be rewarded for high accuracy rates and not for doing as many tests as they possibly can. Perhaps Federal funds should be pegged to laboratories with highest accuracy rates, employees' salaries could certainly be pegged to accuracy rates, and there could be other incentives such as employee of the month bonuses and promotions based on accuracy rates, and also obviously training levels for lab technicians should be strictly regulated. I do not know what the training level of the technician was who performed this test, but certainly there should have been some sort of punishment for him or her. As far as we know, this person is still working at Kingsbrook and has not received any punishment whatsoever.

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[1] See p. 795.

[2] See p. 796.

That is the end of what I have to say.

Senator LEVIN. Ms. Astor, thank you very much, and to you and your husband we are very much in your debt for your willingness to again share publicly your personal agony.

You have indicated that the problem here was apparently a simple mathematical error, either a subtraction or an addition problem of some kind.

Ms. ASTOR. Probably subtraction.

Senator LEVIN. Do you know the level of expertise or experience of that particular technician, whether there was a history of errors for that technician?

Ms. ASTOR. No, we know absolutely nothing at all about the particular technician. We do not know who it was, what the person's training was. We do not even know for sure whether they are still at Kingsbrook. All we know is what Dr. Schneck's initial comment was, that he had decided against firing the technician.

Senator LEVIN. There was a report on Kingsbrook, as I understand it, by the New York State Department of Health, is that correct——

Ms. ASTOR. That is correct.

Senator LEVIN [continuing]. Following this error?

Ms. ASTOR. Yes.

Senator LEVIN. And they had confirmed in that report that there was an error. Did the State Department of Health discuss the lab's performance in general in that report?

Ms. ASTOR. Well, I believe they said that Kingsbrook in general has had a decent record in the past and there apparently have not been too many violations.

Senator LEVIN. Is the Kingsbrook Center a hospital?

Ms. ASTOR. Yes, it is.

Senator LEVIN. And it was subject to regulation by New York?

Ms. ASTOR. It is under New York State regulation, yes.

Senator LEVIN. That is all I have.

Senator COHEN. Perhaps I could, Mr. Chairman, submit for the record a letter that was sent to Mr. Astor, dated January 25, 1988, in which the State of New York indicated that Kingsbrook performed the test correctly but in calculating the final value there was an arithmetic error which was not detected by quality control procedures then in place. The error was not discovered until Dr. Peterson called. Since that time, there has been a computer system installed which will reduce the chance for error in the future. They also have instituted a procedure for spot-checking calculations as an additional quality control step.

Ms. ASTOR. This is something that my husband and I have found very confusing and rather interesting, because we were told at the time that this laboratory error was discovered that Kingsbrook had a spot-checking system at that time. At the time that my husband's laboratory test was analyzed, we were told that one of the reasons it was not caught was because they had no double-checking procedure for every test but they did have a spot-checking procedure.

This letter seems to imply that they did not even have a spot-checking procedure at the time, but that they do now.

Senator **Cohen**. Also, the final paragraph says that, "You have our sincere sympathy in this regrettable"—and then I would emphasize the following words—"and preventable situation." So, apparently the State of New York—which I might point out, has one of the most comprehensive systems of regulation and oversight requirements—found that this was a preventable situation. So this is an extraordinary case in which you have a State which is quite heavily and well regulated, yet a lab made a simple mathematical error. The State came to the conclusion that this was an entirely preventable situation, not something that should fall within the range of error that might be expected. This was entirely preventable, and I think that is an important statement in the letter itself.

Mr. Astor, do you have anything that you would like to add to your wife's statement?

Mr. **Astor**. I was just going to say that with the mathematic calculation that simple, it was so preventable that it could have been prevented in two seconds. Someone just had to look at the worksheet and they would have spotted that 50 minus 25 was 25 and not 35 or whatever the exact thing was then. It would not have even required an extra employee there to check things, it was just so easy to spot if they had looked.

Ms. **Astor**. In addition to that I would like to say that in this particular case the expertise of the technician is not necessarily in question. We do not know what the expertise of the technician was. I think what is at question is the recordkeeping procedures of Kingsbrook, the bureaucratic procedures, if you will. As my husband stated, this error could have been prevented if somebody had just double-checked this technician's work.

I am willing to allow that anybody can make a mistake, even a simple mathematical error, but it is unforgivable that no one double-checked his or her work.

I would also like to say that, although it is not stated in this letter, we were told by an official at the New York State Department of Health that when they conducted the surprise inspection, there was a great deal of difficulty in locating my husband's records, the records of his test, and apparently they felt that there might be some basis for citing them on the basis of sloppy recordkeeping procedures, and I think that is the pertinent point at issue in our case.

Senator **Cohen**. You indicated in your testimony that you had heard that this particular test was performed manually as opposed to being performed by machines. Do you have any basis other than hearsay? Is this something a doctor told you, or the New York State Department of Health told you?

Ms. **Astor**. That is something that the doctor at Columbia-Presbyterian who was conducting all of the tests on us to see if we were carriers for a variant of Tay-Sachs, he told us that.

Mr. ASTOR. He was told by Dr. Schneck at Kingsbrook on the phone and then he relayed that to us, so we heard it second-hand and we cannot verify it personally.

Senator COHEN. Well, I want to join Senator Levin in thanking both of you for coming here today. It is a very difficult situation to articulate your sorrow in public, but we are most appreciative. We hope that something positive will come out of the hearings, so that we can prevent a repetition of the kind of tragedy that you have suffered.

Thank you very much.

Senator LEVIN. Just one additional question before we move to the next panel. I think you said in your written statement that there was a report on Kingsbrook by the State Department of Health. There has been some reference somewhere to a report. Is that the one-page letter from the State Department of Health to you? Is that the report?

Ms. ASTOR. No, there is a fuller report that is available from the New York State Department of Health. This is——

Senator LEVIN. You do not happen to have that with you, do you?

Mr. ASTOR. Our lawyer asked for it and they said it would be a 25- to 35-day delay on it, but it does exist, we just do not have it yet.

Senator LEVIN. Good. Again, our thanks to all of you. We are deeply appreciative of your coming forward. Thank you.

Our next panel includes Patricia Ashton, representing the American Society for Cytotechnology; Dr. George C. Hoffman, who is President of the American Society of Clinical Pathologists; and Judith Barr, who is the Chairwoman of the Governmental Affairs Committee of the American Society of Medical Technology.

We will go in the order that is listed on our witness list here, and first call upon Patricia Ashton. And I would ask each of our witnesses, given the hour, if you could to summarize your statements so that we will have some time for questions.

Ms. Ashton?

TESTIMONY OF PATRICIA ASHTON, REPRESENTING THE AMERICAN SOCIETY FOR CYTOTECHNOLOGY [1]

Ms. ASHTON. Thank you, Mr. Chairman, Senator Cohen and Senator Heinz. I am Pat Ashton, an ASCT-registered cytotechnologist with over 20 years' experience, and I am here today representing the American Society for Cytotechnology.

The inaccuracies in Pap smear testing have been extensively reported in the media. Error rates have been quoted as ranging from five to eighty percent. The ASCT does not think that things are that bad, but we do recognize that a problem exists and must be addressed.

A significant proportion of the errors have been attributed to physician sampling error. The most significant cause of laboratory error, however, is cytotechnologists examining too many smears on a daily basis.

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[1] See p. 138 for Ms. Ashton's prepared statement.

Very simply, when cytotechs evaluate more slides than they can comfortably do, they are going to miss things on the slide. Since approximately 90 percent of the smears are seen only by cytotechs, the potential for error is great when they evaluate too many slides.

The ASCT recommends a daily workload of 80 Pap smears, with a range of 70 to 90 as being acceptable. "Daily" is defined as "within 24 hours".

ASCT members tell us that they are being asked to screen between 100 and 200 slides per day. Why do they do this? They are caught in a Hobson's Choice. They can choose high-volume screening and risk misdiagnosing Pap smears, or screen a manageable case load and risk losing their jobs.

Cytotechs are exploited in the Paps-for-profit cycle. And we have all been lulled into a false sense of security that since the disease, cervical cancer, has traditionally been slow-growing, if the pre-malignant changes are not detected on a smear this year, they will be picked up next year, no harm done.

We no longer have that luxury of time. The behavior of cervical cancer is changing with the epidemic-like incidence of Human Papilloma virus, which has speeded the transit time from normal to full-blown cancer sometimes in less than a year. The disease is occurring in a younger population, and the cytopathology community must react rapidly to these changing events. Next year may be too late.

An excuse we also use is that Pap smears are a screening test. But Dr. Fischer, from whom you will hear later, points out that with a screening test, the clinician may have no other patient information to help identify when a laboratory error may have occurred, and therefore the laboratory result must stand on its own and must therefore be very good.

But our members inform us that they often are not allowed to practice cytotechnology as they were trained to do. A member in California says that where she works, cytotech salaries are based solely on the number of slides they screen per day. If they screen between 91 and 100 slides, they are paid one amount, but if they only screen between 76 and 80 slides, they are paid $2.00 less per hour.

In California, a laboratory may not require a tech to screen more than 100 slides a day, so a financial carrot, if you will, of $1.50 extra per slide is offered to the techs for every slide over 100 which they may evaluate every day.

A member in Pennsylvania reports that a private lab in suburban Pittsburgh pays a piecework rate of 73.5 cents per slide, with a maximum workload of 140 slides per day. The laboratory does not pay Social Security or other benefits.

A suburban Washington laboratory has recently revised its policy, and instead of requiring the techs to evaluate 120 slides per day, they are now expected to evaluate 80 cases, which amounts to just about the same, we are told.

Additionally, if a cytotechnologist is unable to finish 80 cases, or 120 slides, the tech is expected to stay late, until the cases are completed, or have their pay cut. In the past, when this lab was running behind, the techs were encouraged to screen extra slides for overtime and were also encouraged to take slides home for evaluation, which is in violation of Medicare and CLIA regulations.

The education, training and experience of cytotechnologists and pathologists is critical. Cytotechnologists who have successfully completed training in an accredited program, as well as having passed the National Registry examination, can document baseline competency in the discipline. Pathologist training specifically in cytology is not as standardized as that for the cytotechnologist. Only within the last ten years have pathologists been required to have even minimal training in cytology as part of their residency programs.

In addition, we understand that it is possible to fail all the questions relating to cytology on the examination on anatomic pathology administered by the American Board of Pathology and still receive that Board's certification.

Our members tell us that one of the most discouraging parts of practicing cytotechnology is to have completed a rigorous training program and then go to work in a laboratory where the pathologist is not interested in cytology or is not as knowledgeable about cytology as they are.

The techs lose their diagnostic skills when they are not allowed or expected to make diagnoses, but rather, report in nonspecific terms such as "suspicious" or "cancer cannot be excluded". The talent of cytotechnologists is being wasted.

The Federal regulatory program for cytology laboratories is inadequate. The Health Care Financing Administration has been trying to assess the quality of cytology laboratory operations using outdated, process-oriented regulations, surveyors who are unfamiliar with cytology practice and no proficiency testing.

The only way to assure quality is to monitor the diagnostic result. Regulating incoming specimens does not assure outgoing accuracy.

And, just as you would not expect a cytotechnologist to inspect a chemistry laboratory, you should not expect a medical technologist to inspect a cytology laboratory. But this is being done under the current regulations.

There are two voluntary laboratory accreditation programs available to cytology laboratories. The American Society of Cytology's program accredits approximately 50 labs. Although their accreditation criteria cover the important areas of good cytology laboratory practice, their manner of assessing compliance with these criteria is totally subjective.

The laboratory accreditation program of the College of American Pathologists is more widely subscribed to but has weaknesses in the area of cytology. First, the CAP has no workload guidelines for cytotechnologists. Their commitment to this posture was reaffirmed in the March issue of CAP Today.

Secondly, the experience and quality of the inspectors vary widely. Cytotechnologists are infrequently used to assess cytology operations.

And thirdly, the inspectors will converse with the supervisors when evaluating a laboratory, but not with the bench technologists, who really know most about what is going on in the laboratory.

In conclusion, the American Society for Cytotechnology, speaking for the profession, recommends that the following quality assurance methods be made a part of the Federal regulatory program to achieve accurate results which patients should expect and to which they have a right: one, Mandate proficiency testing of cytotechnologists and pathologists; two, workload guidelines based on the ASCT recommendations; three, direct patient billing; four, retrospective re-screening of negative Pap smears from high-risk patients, coupled with histologic and/or clinical correlation studies; five, mandatory continuing education; six, required formal education for cytotechnologists and pathologists; seven, laboratory inspection conducted by trained, professionally experienced cytotechnologists, and finally, required documentation of cytotechnologists' workload, cytotechnologist and pathologist diagnostic accuracy, and clinicians sampling performance.

The ASCT is prepared to work with legislators, regulators and other professional organizations to activate this quality assurance program as soon as possible.

We would also like to submit for the record a paper on recommended changes in Federal regulations for cytopathology, which is concurrently being sent to the Health Care Financing Administration and also a number of letters from our members. We will supply the staff with those copies.[1]

I will be happy to respond to any questions you may have.

Senator LEVIN. Thank you very much, Ms. Ashton, not only for condensing your written statement so well, but also for a particularly and unusually well-detailed written statement. All our written statements today are good, and I do not mean to disparage any of the others by singling yours out, but yours is an exceptionally well-detailed statement and helps us get into other materials. We thank you for that.

Dr. Hoffman is our next witness. George Hoffman is the President of the American Society of Clinical Pathologists.

Dr. Hoffman, thanks for being here.

TESTIMONY OF GEORGE C. HOFFMAN, M.D., PRESIDENT, AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS [1]

Dr. HOFFMAN. Thank you, Mr. Chairman.

I am George Hoffman, a physician, Board-certified in pathology, and President of the American Society of Clinical Pathologists, which is an educational and scientific organization with over 40,000 pathologists, other physicians, clinical scientists, certified technologists and technicians.

I practice myself at the Cleveland Clinic Foundation, a not-for-profit group practice of over 500 salaried physicians in Cleveland, Ohio; and until recently, I was director of the labs there.

With me today is Catherine Cohen, who is the Director of our ASCP Washington Office.

We certainly welcome the opportunity to comment on the quality of clinical laboratory testing and to make some recommendations.

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[1] Available in Subcommittee files.

[2] See p. 152 for Dr. Hoffman's prepared statement.

And, as you requested in the interest of time, I will abbreviate even my abbreviated oral statement.

Senator LEVIN. We call those "compound abbreviations" and we are grateful for them.

Dr. HOFFMAN. As a general statement, we believe that labs approved today, whether under Medicare, through CLIA, or by the College of American Pathologists, produce testing of high quality.

However, we believe that the quality of testing in unregulated settings has not been fully evaluated and that steps should be taken to assure quality testing in these, as in all settings.

Our general belief is that wherever you or I have a lab test, the result of that lab test should be equal whatever the setting in which it is done.

The ASCP is also committed to the view that lab personnel of demonstrated competency are of prime importance in quality assurance, regardless of the setting.

Furthermore, reimbursement must be adequate to permit labs to provide quality testing. There are serious financial disincentives today to producing a quality product, and we have heard an example from my colleague here. Cytology testing, particularly Pap smear testing, is an example of a situation in which problems can arise from such financial pressure.

While amounts paid by patients and third-party payers for Pap smear testing generally may be adequate, most of these payments are made to the ordering physician. A significant percentage of the money paid for Pap smears, therefore, may not be directed to its intended purpose, i.e., to pay for the review of the smear.

Payments ultimately made to the labs for Pap smear testing are insufficient to support the quality of screening the experts have set as standard.

One way of achieving the adequate payment of labs without substantially increasing the costs to patients and third-party payers is to increase the number of Pap smears billed directly by the lab, similar to Medicare's direct billing requirement.

On the question of personnel again, quality in the lab cannot be achieved without quality lab personnel. The lab director has a critical role in determining lab quality through setting standards for quality control and personnel, as well as, of course, the ongoing determination of clinical relevance of all the data.

Non-physician professionals who work in the lab, primarily medical technologists, are responsible for performing many of the tests. The ASCP Board of Registry, established in 1928, is the oldest and largest certification agency for clinical lab personnel, having certified over 278,000 individuals of which 175,000 are medical technologists and 9,000 are cytotechnologists—and I am happy to be sitting next to one right here.

The ASCP medical technologist certification, with its prerequisite of a baccalaureate degree, is a widely-sought label of quality by many labs when hiring personnel. Medicare and CLIA regulations recognize the baccalaureate degree as one of the methods of qualifying as medical technologists.

However, these Federal personnel standards may be reduced substantially in a HCFA lab regulation reform expected to be published in the Federal Register this April.

The potential for increased inaccuracies in testing as a result of such a move is a great concern to the ASCP. This HCFA move to reduce personnel standards conflicts with other efforts in the Department of Health and Human Services to strengthen lab personnel standards—a good example being the proposed standards for drug testing.

The impact of certification, standardized education and clinical experience in lab performance has been empirically demonstrated by a study of medical technologists employed in labs. This study found that labs employing all certified medical technologists produced significantly more accurate results on CAP proficiency testing than did labs employing noncertified medical technologists.

In labs employing both certified and noncertified lab personnel, the study found that "The higher the proportion of certified technologists, the higher the accuracy on CAP surveys."

The impact of the lack of educational requirements for lab personnel on lab accuracy is especially evident in the case of physician office labs. A study by Richard Belsey, M.D. and others on lab instruments used in physician offices found an increased variability in the results when the tests were performed by personnel representatives of those generally found in the physician's office lab.

In the past, there has been no problem in finding adequately trained technologists to work in the lab. Now, however, there are fewer students entering the field of medical technology. This is due in part to the economic pressures on the hospitals, the location of most medical technologist schools, and the concern about occupational exposure to such diseases as AIDS.

Over 25 percent of schools of medical technology have closed since 1982. Cytotechnology schools have been among the hardest-hit, with over 40 percent closed since 1980.

The ASCP asks for your support for a number of mechanisms we are proposing to assist these schools in obtaining Federal funds.

Let me end by emphasizing our major recommendations.

The gaps in regulation of lab testing need to be closed, as you have already stated. The financial pressures on cytology in particular must be alleviated, and Federal standards for lab personnel must be preserved.

I certainly thank you for your time, Mr. Chairman, and I would be more than happy to answer any questions you may have.

Senator **Levin**. Thank you very much, Dr. Hoffman.

Finally on this panel, we have Dr. Judith Barr who, as I indicated, is the Chairperson of the Governmental Affairs Committee of the American Society of Medical Technology.

Dr. Barr.

TESTIMONY OF JUDITH T. BARR, SC.D., CHAIRWOMAN, GOVERNMENTAL AFFAIRS COMMITTEE, AMERICAN SOCIETY OF MEDICAL TECHNOLOGY [1]

Dr. **Barr**. Thank you very much, Mr. Chairman.

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[1] See p. 180 for Dr. Barr's prepared statement.

I am Judith Barr, Associate Dean and Professor of Medical Laboratory Science at Northeastern University in Boston, and I am chairing the Government Affairs Committee for ASMT.

We appreciate the opportunity to present testimony on problems of quality in clinical laboratory services and to share with you our views of the proper role of the Federal government in assuring laboratory quality.

ASMT represents more than 20,000 non-physician clinical laboratory professionals, including clinical laboratory directors, managers, administrators and supervisors.

Central to ASMT's goal is its commitment to the provision of quality clinical laboratory services. We believe that the quality of clinical laboratory services is only as good as the quality of its practitioners, and we now have a major quality problem.

There is a growing volume of laboratory tests being performed in nontraditional labs such as physician office labs, called POLs, where, due to insufficient or nonexistent regulations, improperly-trained personnel are following inadequate quality assurance procedures and producing unreliable and potentially harmful laboratory results.

Recent 1987 data indicate at least 150,000 physicians perform laboratory tests in their offices, most of those offices being unregulated.

Although there are substantial problems of quality in hospital and independent laboratories, ASMT has been asked to address this POL sector. However, in recognition of the problems of quality that do exist in hospital and independent laboratories, the recommendations that follow call for a fundamental and thorough restructuring of regulations for laboratories in all settings.

In preparing for this testimony, ASMT has surveyed many of our members who are employed as consultants for physician office and independent labs, or who act as representatives for various laboratory equipment companies. We have asked them to provide information on three major types of problems they encounter in POLs on a daily basis.

Almost universally, our members have cited: One, the lack of qualified personnel; two, the lack of quality control and quality assurance procedures; and three, inadequate outcome assessments through proficiency testing.

Although many larger group practices may employ medical technologists, the majority of physician offices employing one to five full-time physicians staff their laboratories with non-degreed technical personnel.

A study conducted by the Georgia Department of Human Resources revealed that in solo practice, nurses and other laboratory staff are most likely to perform laboratory testing. Other studies in Ohio and North Carolina report that unqualified personnel, such as nurses, physicians untrained in laboratory procedures, secretaries, relatives and high school students are performing the majority of tests in the group practice POLs.

Several studies recently published in The Journal of the American Medical Association demonstrate a positive correlation between the level of skill of the practitioner performing the test and the quality of that test; the better training of the performer, the better quality of that result.

Comments we have received from our members confirm these findings. Again and again, we have heard that laboratory tests, regardless of the complexity and need for technical expertise, are being performed by individuals untrained in laboratory work.

For example, a medical technologist here in the District of Columbia yesterday told me that her son's cholesterol level on a very sophisticated office analyzer indicated that he had a seriously high cholesterol level. The pediatrician prescribed radical dietary changes that would stress the finances as well as the lifestyle of that family. She lacked confidence in that laboratory test, repeated the test several times in her own hospital laboratory, where the tests were normal.

How many parents have that technical expertise and have that opportunity to take this kind of action to protect their families' health?

Despite technological advantages, even the most simple test such as urinalysis can be misinterpreted. For example, in one laboratory, the unknown expiration date on urinary dipsticks caused a surge of false-positive results, leading healthy women to be improperly diagnosed as having urinary tract infections. In this case, the cost of care increased, and the patient's quality of care decreased.

Microbiology tests that need to use incubators to grow those bacterial cultures are frequently performed improperly by untrained personnel in POLs. One member reported seeing both a POL as well as an independent laboratory using a makeshift incubator consisting of a cardboard box and a light bulb to attempt to simulate the body's temperature.

Another physician in a POL, using the scientific method of sticking his hand in the incubator to monitor the temperature, wondered why he wasn't identifying strep in the patient throat cultures.

Quality assurance and controls are almost completely lacking in POLs. Our members attribute this to cost-conscious physicians who have been misled into believing that quality assurance will affect their profitability and is unnecessary for these maintenance-free pieces of equipment.

Thus it is not surprising that one of the most common problems encountered involves the failure to run standards and controls and to perform regular instrument maintenance. We have heard of personnel failing to change reference ranges with a new lot of reagents; of a kidney specialist who performed sophisticated protein tests without even running controls in his office lab; of a nurse practitioner who left off a standard in performing a liver enzyme test, which resulted in a misdiagnosis for a patient, which then more tragically led to an outbreak of Hepatitis A in a small mountain community.

In POLs, proficiency testing, an important measure of laboratory quality, is virtually unheard of. A recent external quality assurance study performed by the Nebraska Society for Medical Technology confirms that there is substantial cause for alarm about the quality of laboratory performance in POLs. The study revealed that 55 percent of the blood chemistry samples tested by practicing POLs were outside of the normal acceptable range.

Improper performance of laboratory tests, misinterpretation of results, and misdiagnosis exacts a tremendous price on society, not only on our general welfare, but also in terms of health care dollars.

How often are unnecessary, additional laboratory tests run because of a simple, unavoidable error in a routine test? One ASMT consultant reported that repeated questionable results from a blood smear caused a family physician to routinely order costly blood tests which were sent to an outside lab. The cause of these questionable results was a nurse practitioner who, when performing a test, had misread the stain bottle, thus causing many normal cells to appear to be abnormal leukemic cells.

These anecdotes are just the tip of the iceberg. The point should be clear—there are thousands of unregulated and unlicensed POLs; many of them employ unskilled and unqualified personnel to perform what they think to be foolproof laboratory and diagnostic procedures.

Mr. Chairman, there is no such thing as a foolproof laboratory test. Even simple-to-use equipment such as this blood glucose meter that I have right here, just to show you how small and compact they are—as simple as this—produced by companies that really provide good educational and quality control material will not yield accurate results when the person performing that test is not qualified.

A recent occurrence in Great Britain drives this point home. Last fall, a severely diabetic patient died when a nurse in a British hospital placed a blood glucose strip upside-down in the machine.

This is the small strip. There are reagents on it. The blood is placed on that reagent and then placed in the machine in this area. She put the strip upside-down, so that it was improperly read.

This supposedly simple-to-produce result resulted in a fatality. The uninformed action resulted in a falsely low glucose reading. The patient's insulin was discontinued based on this incorrect result, and the patient suffered a severe and fatal diabetic coma.

The incident forced the British Department of Health and Human Services to issue a hazard warning, forbidding individuals uncertified on the instrument to operate it. And this is an instrument that comes with very good manufacturer instructions in quality control. It was just improperly performed.

How many poorly-performed tests resulting in outbreaks of hepatitis, missed urinary tract infections, overlooked strep throats, or other wholly-avoidable threats to the public health, will occur before we take similar action regarding tests in the United States?

This situation in Great Britain affirms ASMT's repeated admonitions to Congress that central to the provision of quality laboratory services are appropriate personnel standards at all levels of practice—and the literature supports our position.

The existing Federal regulatory scheme has failed to ensure uniform quality of laboratory services in all sectors of the service delivery market. The current Federal regulation system is flawed. First, the quality control standards were designed for technologies that are now 20 years old. Much has changed.

Second, current proficiency tests do not measure the everyday level of test performance. They are red-flagged and given special treatment.

Third, regulations are based on the false premise that laboratories in one particular setting could be regulated under separate conditions than laboratories in another setting.

In implementing Federal regulations, HCFA has abrogated responsibility for more than 4,000 inspections to private, voluntary accreditation organizations such as JCHA and CAP, under the guise of equivalency agreements for deemed status. These private physician peer review organizations, which have promulgated self-serving, anti-competitive accreditation standards, have a similarly unimpressive laboratory inspection record.

CAP only denies accreditation to three to five labs per year, readily admitting that it is not an enforcement agency and that it leaves enforcement up to HCFA. The entire inspection process is a subject of grave concern to ASMT, and we urge this Committee to seek empirical data from HCFA and CDC regarding the efficacy of the CAP inspection program and its ability to measure quality laboratory outcome rather than just make organizational structure and process assessments.

From what ASMT members report, the inspection system has the potential for abuse and inherently creates conflicts of interest. Volunteer inspector pathologists are not held accountable for their decisions. And, because the entire inspection process is confidential, it invites opportunities for favoritism and discrimination in the accreditation process.

We have heard that CAP pathologist inspectors frequently enlist their own laboratory staff to serve on the inspection team, thus creating a disincentive for a medical technologist to disagree with her boss' findings.

ASMT members who have been a part of an inspection team report that it is a frequent occurrence for deficiencies identified by a medical technologist to be altered or deleted by others in the final report. Several ASMT non-physician laboratory directors report that CAP inspection at their laboratories tend to be more stringent than at neighboring pathology-directed laboratories.

Some ASMT clinical laboratory director members, fearing reprisals from local inspectors, routinely request out-of-State inspection teams.

One ASMT member who was involved in the inspection of a government laboratory several years ago reported that the inspection team—in this case even including the pathologist—found several serious Phase II deficiencies which were reported to CAP. The team subsequently received a letter from the CAP regional office, implying that the original team did not understand the spirit of the CAP inspection process, and the deficiencies were adjudicated at a local level.

These types of problems raise a serious policy concern. With virtually no Federal oversight of CAP inspections and the cloak of secrecy surrounding them, CAP has no accountability for its actions. It is unclear whether HCFA or CDC performs any random sampling of CAP inspections, and if so, what the results are.

It is a commonly-known fact that CAP is at least three to nine months behind in its inspections, partially due to the lack of pathologists to staff these inspection teams.

There is real fear among ASMT members that CAP is using the organization, its accreditation process, and its request for deemed status to further pathologists' own economic interests and viability and to curtail the ever-increasing presence and power of the nonphysician clinical laboratorians under the guise of quality of control.

ASMT has two concerns directly related to the substitution of private, voluntary accreditation agencies for the government-mandated laboratory inspection process.

First, given that HCFA has passed to CAP and JCAH the responsibility of assuring quality in more than 4,000 laboratories, ASMT urges the Committee to ensure the public's health by validating that these processes do indeed identify problems that exist in the laboratory community. We suggest that this can be accomplished by requiring independent revisits of randomly-selected inspected labs.

Second, given the powerful role of CAP's accreditation program in setting laboratory standards and the political and economic nature of CAP's new director standards, ASMT urges this Committee to examine the new CAP director standards in light of the TEFRA decision and existing antitrust laws.

This has led ASMT into developing a new regulatory policy. Rather than spotty types of policy for different sites, ASMT has proposed a new regulatory model encompassing quality control and assurance, personnel standards, and proficiency testing requirements that would be based upon the complexity and quality of the technology being used, independent of the laboratory performance sites, and this would be applied to all testing locations. It would be linked to complexity of technology, and it would be site-neutral.

The other comments are summarized in both the oral and written comments, and I would like to conclude by saying that our challenge is to assure high-quality laboratory services while respecting diversity where appropriate and standardizing regulations when necessary.

ASMT believes that our model is responsive to that challenge and is targeted at the root of the problem, the quality of the technology and the appropriate personnel to perform and supervise laboratory procedures.

While further study and research will be necessary, we believe that the ASMT model is the first step in assuring uniform and comprehensive laboratory regulation of all sites in which clinical laboratory services are provided.

Thank you.

Senator LEVIN. Dr. Barr, thank you very much.

I have a few questions for each of you. First, Ms. Ashton, how widespread is the problem of cytotechs reviewing more slides than can safely be done in a day, which your organization has estimated at 80, approximately?

Ms. ASHTON. Unfortunately, I think it is very widespread. It occurs in the so-called "Pap mills"; it occurs in smaller, independent labs, and probably less so in hospital laboratories, where cytotechnologists are being requested to screen other kinds of specimens besides Pap smears as well. But it is fairly widespread.

Senator LEVIN. Would you estimate that one-third, two-thirds, one-half—what percentage of cytotechnologists are looking at more than 80 per day?

Ms. ASHTON. I would estimate between one-half and two-thirds.

Senator LEVIN. Okay. Do you have any idea how often the problem of Pap smears being read inaccurately is due to the treating physician taking a poor sample?

Ms. ASHTON. There is a study reported by the Mayo Clinic in reviewing their patients with invasive carcinoma, that 60 percent of the errors were that the cells were not on the slide.

This does not necessarily mean that the physician was at fault in taking the smear. Sometimes patients just do not exfoliate the cells. But 60 percent of the time it was related to the cells just not being present.

Senator LEVIN. Do you think that labs regularly refer back to doctors Pap smears that are taken poorly? Is that a common occurrence?

Ms. ASHTON. Well, the reports that are generated should indicate that the smear is inadequate. Unfortunately, particularly in the very large, competitive laboratories, this is oftentimes not done because of the threat of losing the clinician's business.

I think, again, mainly in hospital laboratories and in some of the better independent laboratories, this process does take place. But many laboratories do not give that information back. The clinicians say, basically, "We don't want to hear that." And the laboratory then succumbs to the wishes of the clinician.

Senator LEVIN. Do you think that Pap smears could be feasibly included in proficiency testing programs?

Ms. ASHTON. Yes, I do.

Senator LEVIN. That is something which you believe is feasible?

Ms. ASHTON. Yes, I do.

Senator LEVIN. And should any Federal proficiency testing program include Pap smears?

Ms. ASHTON. It is my opinion that it should, and the opinion of my organization.

Senator LEVIN. And finally for you, should all Pap smears be reviewed twice?

Ms. ASHTON. No.

Senator LEVIN. And why not?

Ms. ASHTON. That would be an exceptionally large burden on the already-stressed personnel that are working in the laboratory.

We would suggest, however, that a second review be performed on Pap smears that on first review are thought to be negative from high-risk patients. This may put the onus back on the clinicians to assure us, or give us the information that a patient is at high risk. I think the 10 percent re-screen of the general population is nonproductive. If it were a focused re-screening, we would certainly support that.

Senator LEVIN. A few questions for you, Dr. Hoffman.

Do you think that HCFA exercises enough oversight over the accrediting organizations?

Dr. HOFFMAN. Over the accrediting organizations?

Senator **Levin**. Yes—over CAP and over the Joint Commission.

Dr. **Hoffman**. Yes, I think they do. I think, at least from the point of view of JCAH and the CAP accreditation process, that is a very carefully, well-documented, well-worked out operation which HCFA is well aware of.

As to whether HCFA actually exercises its prerogative of re-surveying at any of those actions, I am not aware that they do that.

Senator **Levin**. Now, you have heard Dr. Barr's testimony. I take it you would just disagree with her testimony in this regard?

Dr. **Hoffman**. About?

Senator **Levin**. About HCFA's oversight over the accrediting organizations. You seem to think it is adequate, and I think Dr. Barr has indicated it is not adequate—is that true, Dr. Barr?

Dr. **Barr**. Yes.

Dr. **Hoffman**. Yes, I think Dr. Barr's statements concerning, for instance, particularly the CAP inspections, needs comment. I am quite sure that the CAP, who will be appearing before you tomorrow, are more than capable of doing that, but I would state that as an inspector who has volunteered on dozens of occasions to inspect labs of this sort, that the CAP was the first group to even realize that some degree of standardization and some degree of inspection was needed. The CAP, of which I am also a member, set about organizing such a scheme. The scheme which they set up indeed has standards. The standards, for instance, as far as cytology is concerned, which we have heard a lot about this morning, may perhaps in some areas be inadequate, but they certainly meet the present Federal requirements.

The people who are doing the inspection are doing it as volunteers, and the objective, of course, is to improve the standard of those labs that are inspected.

To say that when you find, to use the technical jargon, a Phase II problem—a Phase II problem being that sort of a deficiency which the CAP will not accredit that lab until it is corrected—is to suggest that these are in some way glossed over, I think, has not occurred, certainly does not occur as far as my knowledge is concerned of the very large number of inspections that I personally have done.

Senator **Levin**. I'll come back to you in a moment.

Dr. Barr, do you want to comment on that?

Dr. **Barr**. Yes. This is based on testimony from our members who have served on CAP inspection teams, from various parts of the country. CAP is central to improving the quality of laboratories, but it also has some potential for abuse when individuals, pathologist teams from neighboring hospitals, visit their friends across town. That is why some of our members are requesting out-of-town visits on the CAP inspection process.

Senator **Levin**. Okay. A couple more questions of you, Dr. Hoffman.

Are proficiency testing programs an accurate way of determining a lab's average performance?

Dr. **Hoffman**. I think proficiency testing is one way to evaluate one part of the lab's performance. One has to remember that——

Senator **Levin**. Is it an adequate way to do it, do you believe?

Dr. **Hoffman**. Yes.

Senator LEVIN. Is it an accurate way of doing it? Is there a better way of doing it? For instance, would they be improved if they were done on a blind basis?

Dr. HOFFMAN. I think in the ultimate, if you could devise a system for double-blind testing what a lab does, it would certainly be a good idea. It is incredibly difficult to do. If you imagine, for instance, sending a specimen in to my lab, to make sure that it goes through the specimen handling, is labelled in such a way that I don't know that it has come in as double-blind—it is fine for me to organize in my own lab, which indeed I do, but it would be very difficult for the CAP or JCAH to organize a system which would accomplish that.

But nevertheless, as an absolute ideal, it would be a good idea.

Senator LEVIN. And would proficiency testing programs be improved if they were done at the same time inspectors visited a lab?

Dr. HOFFMAN. I think proficiency testing has to be an ongoing operation. I think that when a lab is inspected, that is a one-time visit for one or two days, and that one would expect both quality assurance and certainly quality control to be continued on an almost daily basis, depending on the test involved, and that therefore, indeed, you could do quality assurance when you arrived. You could arrive, as we often used to do with CAP inspections, with a specimen, hand it to the operator or the technologist or the pathologist and say, "Tell me what the cholesterol level is in this."

Senator LEVIN. All right.

Senator Cohen.

Senator COHEN. Thank you, Mr. Chairman. I see we have a vote on, so I will try and shorten my questions.

We have an interesting phenomenon taking place, to say the least, where our country is becoming more and more health-conscious. One of the more controversial bills I introduced was one that would have given tax incentives to companies with programs requiring or encouraging people to have annual physical exams, with the hope that there might be a series of tests that could be performed on an annual basis that might lead to early detection of a number of different, potentially fatal, diseases.

That bill was criticized heavily by everybody. It was criticized by the doctors because they said there is no check list that we can think of that would be adequate under the circumstances. The public reaction was overwhelmingly negative, saying it was a bailout for the doctors, and that I was just trying to increase the income for doctors by requiring annual physical exams. So the legislation did not go beyond my pen as a practical matter.

Nonetheless, I was concerned about how we make ourselves more conscious of the types of diseases that can be caught in the early stages.

We have, generally speaking, a much more health-conscious country. People are taking better care of themselves; they are exercising more, changing their diets, stopping smoking if at all possible, reducing alcohol intake, and so forth. We have programs that corporations are now providing in the workplace to increase the health of their employees.

In addition to that, we have doctors who are more and more concerned about malpractice suits. So they are ordering more and more tests. Ironically, we have a situation where people are more health-conscious, asking for more tests; doctors are more litigation-conscious, demanding more tests and ordering more tests. More and more tests are being performed by fewer and fewer people, people who may be qualified but are so overworked that the tests are not being performed adequately.

As a result, we have a situation in which there seems to be less and less supervision. That sounds to me like a prescription for catastrophe for this country. We are all ordering more and more tests and receiving less and less in the way of performance or quality.

Am I overstating the case, Ms. Ashton or Dr. Barr?

If we are talking about having 300 tests per day being performed, it seems to me that assembly line production is taking place, with little supervision.

Ms. ASHTON. I think that is true. There has certainly been abuse in the area of cytology. I think the techs are somewhat to blame. We have been maybe lulled into a false sense of security, as I mentioned in my testimony, but also the disease is not prevalent at a high rate in the population. And techs are devastated when they find they have made a mistake, but they get lulled into a sense of security that they can screen more and more because their errors may go undetected for so long.

Senator COHEN. I am rushing for time's sake, but Dr. Barr, I was interested when you indicated that more physicians are testing in POLs. Is there an assumption that the physicians are actually doing these analyses? That simply is not the case, is it?

Dr. BARR. Physicians do some, but they are as unqualified to do them as the nurses or the high school students who are also doing it.

Senator COHEN. That is another point you made. I think you indicated that secretaries and high school students sometimes do the tests. My staff tells me that there was an ad placed by a doctor who advertised for the services of a technician to do the testing, but who also must do laundry. That is a bold statement that was made. But you have secretaries, cleaning ladies, as well as full-time students doing part-time work in offices.

Dr. BARR. Well, high school students who have absolutely no training at all in doing these test procedures. The link you make with the increased demand on the part of society for health screening and the concern of malpractice by physicians really leads into the whole area of laboratory utilization.

And I think what we have to, as a country, work on is developing what are the appropriate tests for the appropriate conditions. Some of that is done by physicians, some of that is done in the interest of health screening. But as more tests are done, not only is there more cost involved, but there is also more potential for error. And by just the nature of some tests, there is an inherent error rate. If you increase the frequency that you do the test, you are going to increase that error, which is then going to increase further tests and further concerns within families.

The Centers for Disease Control is working with groups to develop this total quality laboratory management concept, and it looks at not just the analytic performance of the test once it gets in the laboratory, but the appropriateness of the test for the clinical condition and the appropriate use of the result as it is being applied to the patient.

So laboratory testing is not just an analytic performance where things can go bump in the night; it is the whole spectrum of laboratory utilization.

Senator COHEN. Do I have it correct that, from your point of view, a physician may not be as qualified as a cytotechnologist to do the examination of the slide?

Dr. BARR. Yes.

Senator COHEN. And a pathologist may not be as competent as the cytotechnologist to do the examination?

Dr. BARR. In cytology?

Ms. ASHTON. I shouldn't say that they are not as qualified. They are not trained to thoroughly evaluate every area on the microscopic slide, and they may not have had as much specialty training in cytology as do the cytotechnologists. That is correct.

Senator COHEN. Now, what if we were to mandate a restriction on how many Pap smears, for example, could be reviewed by a cytotechnologist in one day? Don't we have a problem in doing that? Where do we get the people?

If we have fewer qualified people today, they have very little incentive to go into the profession. What do they make? What does an average cytotechnologist make?

Ms. ASHTON. It varies, of course, countrywide, from about $12,000 per year to $22,000 starting salary depending on geographic location.

Senator COHEN. So we have a situation according to some of the testimony which indicates a lab may charge $1.50, or maybe 50 cents in the case we heard today, for an evaluation of a slide, and then the physician may bill as much as $35.00 for that.

Is that one of the reasons that you recommend direct billing, so that money would go to perhaps either higher pay or greater incentives for cytotechnologists, and less premium would be put on the individual to produce more and more at a faster speed?

Ms. ASHTON. That is correct, and we do have a problem with numbers of personnel, and I think we need to make the field more attractive. The first way to do that is to get rid of this assembly line picture that people feel exists.

Senator COHEN. But we just cannot mandate, saying you cannot do more than 80 in one day. That does not solve the problem, does it?

Ms. ASHTON. Well, there is one other aspect that we have not discussed. We talk about the false-negative rates all the time. It is also my contention that, because of what you brought up, litigation, and the fact that we may interpret cases as being so-called "benign atypia", the Class II that Mr. Johnson referred to, that physicians may be repeating examinations unnecessarily where, if the techs had the time to be accurate in their first interpretation, they would not request a repeat.

So maybe in the area of 10 to 15 percent of the smears that come into laboratories are unnecessary repeats, and therefore—and Dr. Barr addressed this issue as well—more and more——

Senator COHEN. In your written statement you indicate that we should require the documentation of workloads for each cytotechnologist and that the workload requirements be enforced with appropriate sanctions.

How would you address the problem of a cytotechnologist who moonlights? Suppose, we have a restriction on the number of tests during a 24-hour period. But suppose that a person comes off an eight-hour job, is fatigued from the job and decides to take part-time work—how do you deal with that issue? Even though you have mandatory requirements and limitations, how do you deal with a part-time worker?

Ms. **Ashton**. Well, I think it is perfectly fine for a person to do part-time work on the weekend, but not after they have done that—but that is not your question. How do we enforce that? I think it really ought to be put on the laboratory that when they are talking about hiring a person to do this work that they should investigate what that person does the rest of the time, and not be willing to take on an employee who has worked eight hours screening slides.

Senator **Cohen**. What I am getting at is we are really talking about a comprehensive approach to this. We cannot simply look at some sort of mandatory restrictions or imposition of sanctions without looking at some of the problems caused as a result of this. If we put restrictions on how many tests, we still have to deal with the rising demand for more and more tests. We have to deal with the problem of the cytotechnologist maybe not receiving enough money, not enough incentive, so we have fewer people going into the field, and we have to resort to less-qualified people.

We really have to take a very comprehensive approach to this, otherwise we give the appearance that we are dealing with it by passing legislation which will be counterproductive, ultimately. That is one of the concerns I think Senator Levin and I are trying to deal with—exactly what should be the role of the Federal Government? How comprehensive do we have to be?

Dr. Hoffman, you would like to have deemed status given to the CAP. I think Dr. Barr might disagree with why we should do that, since the CAP is not an enforcement agency, it does not engage in regulation, it does not for the most part deal with sanctions. So the question is why should we give deemed status to CAP under the circumstances?

Dr. **Hoffman**. Is that a question for me?

Senator **Cohen**. That is a question, sir, yes.

Dr. **Hoffman**. I could, I suppose, duck that and say you should ask that of the CAP representatives who are going to be testifying tomorrow. But I would again impress upon you that when you state concerning sanctions that the CAP does not take any action when it sees faults, I think that that is an overstatement, because there is no way that a lab which does have deficiencies of a serious nature will be accredited by CAP.

Senator **Cohen**. Well, I guess the question is once a lab is accredited, what takes place then? How often is the lab reviewed? Is it once every year, once every two years, once every three years? What has been the record of those labs that have been certified or accredited being suspended for having inadequate standards or performance ratings?

Dr. **Hoffman**. I may get stabbed by my CAD colleagues.

Senator COHEN. Okay. I don't want to misdirect the question.

Dr. HOFFMAN. No, no, I'd be more than happy to try and answer that. I think that obviously, one could take the argument as to how often you should inspect a lab to a ridiculous conclusion. If you inspect a lab today, it might make a mistake tomorrow, so you have to have some cost-effective approach as to the number of inspections.

CAP has chosen the approach that you inspect on-site every 2 years. Today you inspect my lab: if you find some deficiencies I have to provide written documentation that I have corrected those, and they have to see to it that I have corrected them. They then give me accreditation.

Once I am accredited, they will inspect me on-site again in 2 years, but in the alternate years, I have to fill out a self-inspection, which is entirely the same documents that they would fill out when they visit.

But that single inspection covers a lot of things which are important, but are unlikely to change—the air conditioning, the fire safety, the number of technologists you have there, evidence that they have post-graduate training, and this, that and the other.

As far as the functioning of the lab and actually running the test, what is equally important and what the CAP insists on for their accreditation is that those labs take part in their quality assurance PT, which again is a program which varies with the subspecialty in the lab to see how they do on those particular tests.

And then, even more important, the CAP insists that there is evidence that internal quality control is taken on every test, every day, every time it is run.

To give you an example, I checked before I came here. In my particular corner of the lab—I am a hematologist by interest and training—almost twenty percent of the effort in that lab goes into quality control. Or, to put it briefly, one in twenty of every test we run is a quality control test.

So you have the whole spectrum from the once a year inspection of the whole lab in a complete manner, as to whether the professional's including both the pathologists and the technologists, of course, and others, are looking at the institution, the relationship with the clinicians and all these sorts of things, once a year.

But all these three tiers of efforts are vital and are essential, and I think that the problem, as has been pointed out is with the physicians' office lab. One thing that one could do is to state that they indeed also should have written evidence of quality control, that they have gone through quality assurance, and most particularly, that the personnel who work in there meet at least minimum requirements and have some documented proficiency in doing their job.

Senator COHEN. Let me turn to Dr. Barr. You mentioned the words, "red flag," during your testimony. Would you explain for us what you mean by the red-flagging that may take place with proficiency testing samples in a lab?

Dr. BARR. Typically, when a laboratory receives a proficiency testing sample, it is known to the laboratory that their accreditation or their license depends on the accurate identification of the organization or the quantification of what that specimen is. So it is given usually to the most qualified technologist in the laboratory, where it is repeatedly performed, and sometimes there is an informal network of technologists calling technologists in different hospitals to say, "What did you get on that proficiency testing sample?" to see whether they are in the right ball park, because the likelihood of the accreditation or the State licensure depends on acceptable performance on that proficiency testing sample.

Senator COHEN. If this is a common practice, then what purpose does PT serve?

Dr. BARR. What it serves is to show the best possible quality of that laboratory, so that if a laboratory has trouble with PT, it has big trouble. To then assess the everyday laboratory performance, some way of doing blinded assessments, or when inspections come, to just randomly give the specimen to any technologist–there have to be ways developed that can measure the more routine performance in the laboratory rather than the special attention, optimal capacity capability of that laboratory.

Senator COHEN. Ms. Ashton, is the Centers for Disease Control doing enough to develop proficiency testing for Pap smears?

Ms. ASHTON. It would appear that they are not at the present time, Senator Cohen. They have had an ongoing program on an experimental basis for the last 15 years, but yet the powers that be in another branch of the CDC seem to feel that proficiency testing is not possible in cytology and do not seem to be making any attempt to develop such a program.

Senator COHEN. Dr. Barr, I think in your testimony you indicated that the Federal government should not formulate another regulatory system based upon a particular disease or clinical condition such as that proposed for drug testing by the National Institute for Drug Abuse.

Do you think there is any justification for stricter standards for drug testing than other types of lab tests?

Dr. BARR. ASMT is not in support of disease-specific regulations. We believe that a laboratory test, independent of its site of performance or type of analysis, should be based on the technology, the quality of the people.

So we are not supportive of either disease-specific or analyte-specific sets of regulations.

Senator COHEN. How about AIDS?

Dr. BARR. The laboratories would then have to meet the qualifications that go along with the technology. The technology currently requires qualified people, proficiency testing, quality control, and so it would fit into the ASMT model of Level III, requiring qualified medical technologists with technology and proficiency testing appropriate for the technology of test performance.

Senator COHEN. Dr. Hoffman, you wanted to say something.

Dr. HOFFMAN. Excuse me, Senator. I'd like to just comment on your question about establishing of quality assurance for cytology.

The difficulty here is if you are setting up quality assurance for a particular analyte that is known, like measuring shall we say sodium in urine, the technology is exactly known, and you know that the right answer is "x".

On the other hand, when you screen a Pap smear, what you now are looking at it somebody's perception of what is down at the end of the microscope. Now it becomes very difficult to develop a quality assurance program which will test all parts of that Pap smear testing from obtaining the specimen to the final interpretation made by the pathologist to the gynecologist.

It is possible, however, and the ASCP amongst many others is at this very moment trying to develop in conjunction with the American Society of Cytology, such a program. But it is very difficult to try and find what would be—thousand—slides, all of which would have to be identical, to pass around to see how people were doing.

So it has to be done on the basis of a series of slides going to different people, perhaps, as one way of doing this.

I think to answer your question briefly, though, it can be done and it should be developed.

Ms. ASHTON. May I comment on that, Senator Cohen?

Senator COHEN. Yes.

Ms. ASHTON. I would agree with Dr. Hoffman, but there are new technologies that we might look into such as videodisc technology, we have quite a large collection of slides that the CDC has accumulated over the years of well-refereed cases that are histologically documented. These cases could be transferred to videodisc and the technologists and pathologists then look at the same cells, the same cases throughout the country. I think this is a methodology we need to look at.

Senator COHEN. We are going to have to go over and vote, but just one other final point on the question of liability.

As the situation is, the patient comes to the physician and relies upon the physicians' training and education and integrity and reputation in the community in submitting to his or her treatment. That physician in turn relies upon tests done by the laboratories. When there is a mistake or there is negligence, the suit is brought against either the laboratory or the hospital, if it is a lab in a hospital, and the physician has no responsibility, generally speaking.

Now, with the proliferation and expansion of POLs, it seems to me that physicians will bear the responsibility for those tests that are being conducted. To the extent that there is a proliferation of these POLs, it seems to me that there has to be some sort of standards being set at the State level and/or the Federal level.

There is a greater assumption of responsibility with more and more tests being done in the POLs.

I have more questions; it will take about two hours, Mr. Chairman. But we have another panel to go, and we have a vote on at this point.

Senator LEVIN. This is what we will do: I just have one or two more questions. If you are able, Senator Cohen, why don't you leave and vote now? I will try to stay until about five after, and if you are not back by then, I will just adjourn.

Just one question for you, Dr. Hoffman, and that has to do with whether there is anything reasonable that you believe we, the Federal Government, the Congress, can do which would reduce the likelihood of lab error?

First, focus on the Congress. The other witnesses on this panel have basically made a number of specific suggestions to us as to what actions should be taken to reduce the likelihood of error which, in their view, are reasonable for us to do. Can you tell us if there is anything that you believe Congress can do to reduce the rate of error which would be reasonable for us to do?

Dr. HOFFMAN. I think in order to reduce error, you have to prove and demonstrate competency in that lab or office where the tests are being done. Therefore, I think the one thing that would be relatively simple to do would be to see to it that the individuals working in that lab, both the physician and his technologist or technician, have certain competency characteristics, that they have continuing education, and perhaps most important, that they should take part in a proficiency testing system of some sort, which at the moment is not the case in many of these what we are referring to here as unregulated labs.

Senator LEVIN. All right.

Do any of you believe that we could reverse the proficiency testing approach? That is, instead of sending a sample to a lab to be tested, do the reverse—take samples from labs which have already been tested and to double check them independently at other labs? Has there been any suggestion that we do that type of proficiency testing, and does it make any sense to any of you? Is that a practical approach to proficiency testing?

Dr. HOFFMAN. Very quickly, in a sense, it certainly is. It is like using a reference lab to double-check other labs. The only problem is, of course, that it is only checking one part of the whole lab process. And one thing we have not touched on at all here is the importance not of the result of the test, but the actual choice of the test that you do.

Senator LEVIN. All right. So you do not see that approach as a big, practical plus; is that a fair summary?

Dr. HOFFMAN. I think that is a fair statement.

Senator LEVIN. Do either of you see any significant, practical pluses in adding that kind of proficiency testing to what already exists?

Dr. BARR. It has the same potential of the red flag that you will do it multiple times before you send it out to make sure that you are very comfortable with the results—again, the best capacity and capability of that lab, not necessarily the average daily quality of that lab.

Senator LEVIN. Ms. Ashton?

Ms. ASHTON. It could be done to a certain extent in cytology. The material would be available. It would have to be a blind sampling——

Senator LEVIN. Yes.

Ms. ASHTON [continuing]. And the laboratory who was doing the review would be able to detect that it was not coming from their laboratory. So it would not be totally blind.

Senator LEVIN. Okay. Just one last question, Dr. Barr. Does HCFA make available to the public information, if there is any, about the findings and actions of the Joint Commission or CAP? Is this information made available to the public by HCFA, do you know?

Dr. BARR. Not that I personally know of.

Senator LEVIN. We thank you all. There may be additional questions that we will have for you for the record that we would appreciate your answering. You have all been very helpful in your testimony. Thank you.

We are going to introduce our third panel here, and then I will leave in just a couple of minutes to make this vote.

There are two members of the third panel this morning. Dr. Paul Fischer is Associate Professor of the Department of Family Medicine of the Medical College of Georgia; and Virginia Worrest is a consultant from Corvallis, Oregon.

Dr. Fischer, why don't you start? I may interrupt you in about a minute and a half if Senator Cohen is not back by then and just adjourn for a few moments. But why don't you begin?

TESTIMONY OF PAUL FISCHER, M.D., ASSOCIATE PROFESSOR, DEPARTMENT OF FAMILY MEDICINE, MEDICAL COLLEGE OF GEORGIA [1]

Dr. FISCHER. Thank you very much.

For the past seven years, I have served as an "office laboratory director", first in solo practice in Weeping Water, Nebraska, and then at the Family Practice Center in the Medical College of Georgia.

When I first used this term, "office laboratory director", some individuals in the laboratory community thought that it was strange, since they did not believe that the office laboratories were "real" laboratories.

Clinicians had a similar quizzical response. They said to me, "I don't have an office laboratory, I just do a little testing."

What I would like to do for the next few minutes is to describe the office laboratory environment from a clinician's perspective, and unlike many people who have an opinion on this subject, I spend time every day in an office lab.

There have been a variety of reasons cited as explanations for why physicians do office testing. I believe that for most clinicians, the overriding concern is to provide high-quality and efficiently-managed patient care.

Let me give you a quick example of how office testing can improve patient care.

Suppose that you came to my office five years ago and had a problem with asthma. Theophylline is one of the common medications used to treat this illness. A serum theophylline level is used to monitor the drug dosage to be sure that enough drug is prescribed, but not too much as to cause patient harm.

If you came into my office five years ago and were on theophylline and had wheezing, I would have drawn a theophylline level and sent it off to an outside reference laboratory. I would have been hesitant to increase the drug dosage since this could lead to toxic side effects.

Senator LEVIN. I am afraid, Doctor, I am going to have to interrupt you if I am going to make this vote. Senator Cohen is a fast runner, but apparently not that fast. So we are going to recess for a few moments until Senator Cohen returns. And again, my thanks for your patience and understanding.

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[1] See p. 219 for Dr. Fischer's prepared statement.

[Short recess.]

Senator **Cohen**. The Subcommittee will come to order.

Dr. Fischer, I believe we should hear from you first. If you could summarize your testimony, we will then move to Ms. Worrest, and then I will ask a few questions and we will move on to the final panel.

Dr. Fischer.

Dr. **Fischer**. Okay. I was in the middle of describing why clinicians do office testing, and I have been asked by your staff to answer five questions about office laboratory testing.

Let me begin by giving you a quick example of how office testing can improve patient care.

Suppose you came to my office five years ago and you had a problem with asthma. Theophylline is one of the common medications used to treat this illness. A serum theophylline level is often used to monitor the drug dosage to be sure that enough drug is prescribed, but not so much that it would cause patient harm.

If you came to my office five years ago and were on theophylline and had wheezing, I would have drawn a theophylline level and sent it off to an outside reference laboratory. I would have been hesitant to increase the drug dosage, since this could lead to toxic side effects. If we were lucky, the blood would have been picked up by the reference laboratory on time, tested appropriately, and the results mailed back to my office.

Three or four days after your visit, I would have called you up to tell you that the test had indicated that your drug level was low and that you needed to be on a higher dosage of theophylline. You would wheeze in agreement and complain about the test delay.

The testing process and its associated inconvenience would have been frustrating for you and for me.

If the same patient came to my office today, I would do an office theophylline test and have the results in 20 minutes. The drug dosage could be adjusted immediately, if indicated. This rapid office testing provides better care to the patient and saves my spending time following up on the laboratory result two to three days after the patient's visit.

The average time for a physician to follow up on a laboratory test has been estimated to be about 14 minutes. This includes time reviewing the result, contacting the patient, calling the pharmacy, and writing a new note in the medical record.

It is easy to see how office testing can improve the efficiency of patient care and therefore, why physicians are interested in its development.

The big question is: How good is office testing?

Well, there is a lot of anecdotal data, and following Dr. Barr, that is pretty obvious. We unfortunately have very little direct data to answer this question. This is in large part because there has been almost no funding of research in this area. The only direct data come from the proficiency testing programs which are organized by professional groups, the diagnostic industry, and a few State health departments.

The published data from the ASIM and CAP proficiency testing programs indicate that the testing in participating office laboratories is actually very good and in most cases is comparable to the testing in hospital and reference laboratories.

Unfortunately, the total number of laboratories which participate in these various PT programs is less than ten thousand.

Senator **Cohen**. Dr. Fischer, ten thousand equals what, ten percent?

Dr. **Fischer**. It is about ten percent of all office laboratories, and it is likely that these laboratories are not representative of the other ninety thousand office labs.

A laboratory which voluntary participates in PT is usually a very good lab, and PT is the principal way that laboratories assure the external validity of their results. The fact that most office laboratories do not participate in PT is therefore indirect evidence, in my opinion, that there may be some problems with office testing.

There are two other types of indirect evidence. The first is the fact that most office testing is done by people without formal laboratory training. These include nurses, medical assistants and receptionists. Most surveys of office laboratories have indicated that about thirty percent have formally trained personnel.

In a study which we did in Georgia in cooperation with and with funding from the CDC, we asked for the credentials of everyone in the office who did any testing. When these data were analyzed, we found that about ten percent of these persons had some formal laboratory training. It is likely that the informal training of the remaining ninety percent is quite variable.

The final piece of indirect evidence is the fact that there are almost no educational programs available to teach clinicians or their staff about what is needed to produce good laboratory testing. In a national study, which we conducted in family medicine residency programs, only fifteen percent of residence programs had any formal training in laboratory management. Despite this low percentage, family medicine has been more attentive to the laboratory training needs of their residents than any of the other clinical disciplines.

The next question is: How effective are the State regulations?

While fourteen States have adopted some regulation of office laboratories, it should be recognized that these regulations have had only a limited impact. The regulations in fact are often written to exclude most of the real office laboratories.

The administrative resources which are allocated are usually very limited, and the regulations often lack effective penalties. They are to a large extent regulations of convenience. This has been necessary because office laboratory regulation, in the usual sense of that word "regulation" is a huge and complex task. Those States which have had the biggest impact on office test quality are probably Idaho and Pennsylvania. In these two State programs, the regulatory staff have principally taken on an educational rather than a regulatory role. And Jo Bartola from Pennsylvania will be talking to you a little later.

Next question: What are the components of an ideal program for office laboratories?

Thirty years ago, hospital and reference laboratories had major problems with the quality of their testing. A variety of regulatory mechanisms were therefore instituted. The principles of these mechanisms are appropriate for an office laboratory program, but it should be emphasized that the details are likely to be very different. An office laboratory is not just a small hospital laboratory.

The usual cited program components include: education, personnel, proficiency testing, on-site inspection, required quality controls. Let me address each of these.

First, education. Most physicians want to provide good patient care and therefore want to do good testing in their laboratory. However, to a large extent the current training of physicians does not provide them with the skills necessary to direct a laboratory nor to recognize when poor testing is being done. Clinician education must therefore be at the center of any office laboratory program.

Next, personnel. Rigid personnel standards are an impractical solution. It is appropriate for nurses and medical assistants to do some types of testing. Technology now exists which permits reliable testing by people without years of laboratory training. This same technology permits any woman in America to buy a pregnancy kit from her pharmacy and to diagnose her own pregnancy in the privacy of her "bathroom laboratory". If the technology is good enough for the public, it is certainly suited for the nurse working under the supervision of a physician in an office laboratory.

Senator **Cohen**. Could you stop there for a moment? Do you mean you would extrapolate from the pregnancy test to any other type of equipment that might be on the market for individuals to conduct their own tests?

I am not sure what you mean by saying that—if they have a test kit they can perform in their own "bathroom laboratory", we certainly should have no stricter standard for that of a physician's office.

Are you extrapolating to say whatever is on the market, that is an indication that it is acceptable to perform that test in the private laboratory of the individual, and therefore we should be able to do it in the physician's office as well?

Dr. **Fischer**. I would not make that argument at all. The FDA has an entirely different set of guidelines that it goes through when looking at over-the-counter testing. Some of those things are applicable for office testing, and some are not.

I disagree with the ASMT approach in basing this solely on technology, because after all, the technology currently available to test for AIDS, to test for strep in the office or even pregnancy tests are very similar technologies.

On the other hand, I would make a distinction between those laboratories doing AIDS testing and those laboratories doing pregnancy testing, because of the severity of the diagnosis.

So I think the clinical context of the information is probably the most important step, and that is where drug testing and AIDS testing take on an entirely different severity for me.

Next, proficiency testing. This testing permits the clinician to compare the office laboratory's results with that of any other similar laboratories. It has only been very recent that any proficiency testing program suitable for office laboratories has existed. Required proficiency testing and suitable performance on this testing are probably the most efficient regulatory components to any proposed office laboratory program.

On-site inspection. It would obviously be impossible to regularly inspect the one hundred thousand office laboratories. In addition to being impossible, I believe it is unnecessary. An ideal program should identify laboratories which have problems and focus the expensive resource of on-site inspection on those laboratories. Above all else, inspection is an educational intervention.

And finally, quality control. Quality control procedures are those things which a laboratory does every day to be sure that its testing is good. The specific recommendations for good quality, as it is now practiced in hospital and reference laboratories, is to a large extent dogma, reinforced by habit, and has little to do with the stability of today's test systems.

Many hospital and reference laboratories practice overkill in quality control. More is not necessarily better; enough is enough. Any recommendations for quality control in an office laboratory program should be based on the stability of the test, the qualifications of the intended user, and the clinical context in which the test data will be used. The latter is often of little concern to hospital reference laboratories. It is, however, at the heart of the clinician's concerns.

The principles of quality control in an office laboratory program will be the same as those in any other laboratory. However, the details should be quite different.

Finally, what is the government's role in regulatory office laboratories? I believe we are at the beginning of an evolutionary process, and that this will take three to five years and should lead to a marked improvement in the quality of office testing.

There are no inherent reasons why testing in a physician's office should not be as good as laboratory testing at any other site. To support these evolutionary changes, I believe the Federal government should do several things.

First, it should fund research which examines the quality of office testing. The government is responsible for developing regulations when there is a public health risk. At this point in time, there are too few data to know the risk from office testing. One would be establishing policy in a vacuum without knowing more about the problem as it now exists.

Second, there should be funding for the development of demonstration projects aimed at improving office laboratory testing. Support for a project like COLA, which will be described tomorrow, would be a good first step.

And finally, it is my opinion that the best regulation is threatened regulation, and threatened regulation will likely serve as an impetus to the diagnostic industry, to clinicians, to professional societies, and to State governments to resolve the problems associated with office laboratory testing.

If, after a reasonable period of time, this evolution in office laboratories has not occurred, it would be in the public's best interest to establish a Federal regulatory system. By that time, there should be more information, so that it would be clearer how to put together an effective and reasonable regulatory program.

The changes in technology and the restructuring of health care delivery have contributed to the decentralization of laboratory testing. Your home bathroom laboratory can now do tests that were not even possible for hospital laboratories ten years ago. This process will continue, and it should be managed.

Senator COHEN. Dr. Fischer, thank you very much. Let me ask you, if we threaten regulation, how much of a percentage increase do you feel that it will have in terms of those physician labs that would agree to proficiency testing on a voluntary basis. I think you indicated ten thousand out of the total number, which is ten percent. How much do you expect that to go up if Senator Levin and I suggest that there may be an impending flood tide of regulation coming?

Dr. FISCHER. This is an area I have worked on about ten years, and the activity on the Hill and in the press in the last few months has done more to improve the situation than I have been able to do for a long time. So I certainly would not be against you threatening that, and I think you would probably find that professional societies would support it to a large extent, encourage their membership to follow with it, and that that might well lead to a very high percentage of office labs participating.

Senator COHEN. Why have there been so few, on a percentage basis, of physician labs voluntarily agreeing to proficiency testing?

Dr. FISCHER. Most clinicians do not know what proficiency testing is. They have never worked in a lab where that was done. They are not given any training to know what is required to do good testing. It is an educational—

Senator COHEN. Why would physicians not want to participate in this voluntary program—why do so few participate?

Dr. FISCHER. People do not like to change. I think it is as simple as that.

Senator COHEN. All right. You mentioned before that we could perhaps have various types of tests performed in the doctor's lab or a patient's own home bathroom lab. What about Pap smears being read in physicians' offices, is that troublesome for you?

Dr. FISCHER. Let me address that in two ways. First of all, there really needs to be a separation of those tests which are screening tests in which the physician has no clinical information to add to the test, and the two examples you used today were screening tests. One was screening for genetic disease, the other for cervical cancer. In that scenario, the doctor is really handcuffed, and he has to go by the lab test.

Those tests need to have a different standard set, principally because the doctor is relying on them.

The second thing is that there has been some confusion about whether office labs do Pap smears. In offices where Pap smear specimens are collected, I have only seen one office lab where the test was actually read, and in that setting, the doctor had been a cytotechnologist before going to medical school.

Office labs are not doing Pap smears.

Senator COHEN. The question is number one would it be appropriate; and number two, if it is appropriate, should it be regulated?

Dr. **Fischer**. There are a couple areas of testing which are very problematic. Pap smears are certainly at the top of the list. Cholesterol testing is number two.

Senator **Cohen**. I am not sure you answered my question. Do you think they are appropriate to be conducted in an office lab?

Dr. **Fischer**. Pap smears are not done in office labs.

Senator **Cohen**. Well, you are saying they are not; should they be?

Dr. **Fischer**. The technology does not permit people to do it now in office labs. If there were different technology, some kind of an antibody that determined—all you had to do was see a blue dot or not—then screening for cervical cancer would be fine. We screen for colon cancer by looking for blood in the stool very commonly in office labs. At this point, the technology is not appropriate for an office lab.

Senator **Cohen**. Senator Heinz mentioned legislation which was passed as recently as last December that the Medicare independent lab standards are scheduled to be applied in 1990 to those physicians performing over five thousand lab tests. This cut-off is a matter of some debate. There are some who feel it is too high and others who feel it is too low. What is your assessment?

Dr. **Fischer**. I think a cut-off is irrelevant. That cut-off would include most office laboratories as they now exist in primary care settings. The intention of that cut-off is fine. The labs that do smaller volumes, though, tend to have more problems, so I don't find the cut-off really meets the need in terms of public health.

Senator **Cohen**. You mean if you have more tests, the error for margin is not increased?

Dr. **Fischer**. The labs that are doing more tests are inclined to hire trained people; they therefore have a higher quality of testing.

You could make a good argument that any lab doing less than five thousand would be the one that the government would really be more interested in.

Senator **Cohen**. Well, how would you factor that in—if the purpose is to slow down the number of tests that are being conducted so that they have more time to read them, wouldn't it follow logically that with fewer tests, you might have more caution taken and perhaps more professionalism, as opposed to running through a higher figure?

I understand what you are saying, that if you do fewer tests, the staff may not be as competent. Therefore, perhaps these labs ought to be subject to more regulation. But you can also make a counterargument saying that the slower the process, the more careful and the more responsible.

Dr. **Fischer**. I think that is an important aspect for the Pap smear problem in a large reference lab. In an office setting, generally, the person doing testing is spending time drawing blood, putting a patient in a room, taking blood pressure, and a variety of things like that, and this issue of eighty tests a day is not really germane to that setting.

Senator **Cohen**. So you think it is irrelevant in terms of the cutoff figure itself?

Dr. **Fischer**. I don't think that is a very wise approach to this problem.

Senator **Cohen**. Okay. Should personnel standards be imposed on physician office labs that perform certain types of tests which require a greater degree of training in laboratory practices?

Dr. **Fischer**. I wouldn't be opposed to that—for example, if a lab were doing therapeutic drug monitoring—I am sorry—drug abuse monitoring or AIDS testing or Pap smear testing. These things have very important effects on how we take care of patients. And under those situations, you could argue that certification of personnel would be appropriate.

Senator **Cohen**. How about cholesterol—you left that one out.

Dr. **Fischer**. It is an issue both of the clinical relevancy and also of the technological feasibility, and at this point, there are instruments in the office setting where cholesterol can be easily done.

Senator **Cohen**. All right. Let me move on.

Ms. Worrest, would you offer some of your comments about the study that you were a part of?

TESTIMONY OF VIRGINIA L. WORREST, CONSULTANT, CORVALLIS, OR [1]

Ms. **Worrest**. Mr. Chairman, good afternoon.

I am Virginia Worrest, President of Chalet Associates, a medical technology consultant firm in Corvallis, Oregon. I am currently a candidate for a master's degree in interdisciplinary studies at Oregon State University; registered with the American Society for Clinical Pathology; and certified by the National Certification Agency for Medical Laboratory Personnel.

I was one of four medical technologists hired in 1986 by the State of Oregon Public Health Laboratory to survey physician office laboratories, the granting agency being Centers for Disease Control in Atlanta, Georgia. Grants were also given to the States of Georgia, North Dakota, and West Virginia.

The object of our study was to determine whether educational materials supplied to physician office laboratory personnel is a feasible means for effecting improvements in the performance of microbiology testing by POLs. Additionally, we were to survey the scope of testing in these facilities, how the testing was being done, and by whom.

Forty unlicensed POLs and twenty State licensed POLs were included in the study. I would like to stress that participation on the part of the forty unlicensed POLs was totally voluntary. So in going into these laboratories, we surveyors expected to find procedures very much in order.

I conducted three different on-site surveys in twelve POLs in two specific areas of the State over a period of a year. Of the approximately forty people responsible for laboratory testing in these twelve POLs, only two were registered medical technologists.

Upon completion of this study, and after much moral consideration, I made a conscious choice for my firm. We now no longer accept consulting jobs when the client is an unlicensed physician office laboratory.

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[1] See p. 224 for Dr. Worrest's prepared statement.

Upon doing an environmental scan of unlicensed POLs, I find that the climate is much the same as it was in hospital laboratories and the emerging profession in general thirty years ago when I became a medical technologist. There is an almost total lack of adherence to any type of quality control or proficiency testing program.

This, of course, was corrected to a great extent in the hospital laboratories with various regulatory mechanisms, especially in the last twenty years.

As for testing currently performed in unlicensed POLs, quality assurance is virtually nonexistent. Compounding the problem is the lack of personnel standards in the POLs. Other than the physician's own interpretation as to what credentials these people must have, there are none.

Many of these physicians have very little interest in the laboratory and know nothing about the different types of laboratory personnel, the subtleties of testing, the idiosyncratic personalities of supposedly foolproof electronic equipment, or even the basic concepts of quality control.

In today's laboratory marketplace, the physician has available to him or her an array of analytical systems offering walk-way, black box technology which occurs when the operator merely push-buttons, and the results are usually read or interpreted directly from the analytic system.

Resources to develop laboratory expertise are not readily available to them or the other personnel who supervise POL laboratory testing, such as a nurse or a receptionist, who often find the responsibilities for laboratory testing only incidental to the major focus of their responsibilities—that of direct patient care activities.

I offer the following example. I observed a case where a doctor transported his incubator, used to grow bacteria, between his country home office and the town office, electrically plugging it in when needed for a throat culture for the purpose of ruling out a strep throat.

No temperature check was ever made, even though the streptococcus grows at an optimum of 35 to 37 degrees Centigrade, with the possibility of unsatisfactory growth at a few degrees above or below this, which can yield results interpreted as negative.

Also, the doctor asked me to convey to the State laboratory the fact that microorganism samples received from the State to be tested for determination of his laboratory's accuracy did not grow and that "there must be something wrong with the specimens they sent."

Shortly after this comment, I overheard this doctor in the next room with a returning patient—a small boy who still had his sore throat. The boy was told that it must be a virus, because his throat culture was negative, and no antibiotics were needed for treatment because they only would work for a strep throat.

It was only in discussion with the physician immediately following that I mentioned his totally inadequate method of incubation of throat cultures, that the doctor truly realized the possibility of a misdiagnosis.

I have wondered many times since this experience if that little boy actually had a strep throat, and if so, would it have gone on to cause a disease as severe, for instance, as rheumatic fever, incapacitating him for a long time, not to mention prophylactic antibiotic treatment for the rest of his life, and changing the quality and possibly the longevity of his life—and what of the emotional burden to his family and the financial burden to his insurance company if he had insurance, and to the entire health care system?

My observation was that this doctor was very intelligent, a very caring doctor, working for an unbelievably low amount of money in a depressed area. His charge for the laboratory work to the patient was very low, if existent at all, depending upon the ability to pay.

But his understanding of laboratory quality control has never been grasped nor learned. Also responsible for doing microbiology in this POL were the doctor's receptionist, cleaning woman, and a high school student who came in after school. They were trained on-the-job by the doctor, who was considered the director of the laboratory.

This situation is entirely legal in most of the States in this country.

It is not an exception that in one area I surveyed, less than half of all of the unlicensed physician office laboratories ever made temperature checks of their laboratory incubators. The percentage for the State-licensed POLs was one hundred percent. And not one unlicensed laboratory made quality control checks on the media used for growth of throat culture specimens.

Even more revealing was the fact that only eighteen percent of the unlicensed POLs in this survey participated in proficiency testing programs in microbiology or chemistry or hematology. Again, the licensed laboratory percentage was one hundred percent participation.

Participation in such a program is a relatively simple and inexpensive means of intervention which would considerably reduce the variability in physician office testing. I might add that, having set up my first physician office laboratory in Massachusetts in the early 1960s, this is not a problem of POLs just in Oregon, but has been a growing trend nationwide.

Case Number Two. The product of the clinical chemistry laboratory is test results that are used for diagnosis and treatment of disease. I surveyed a POL whose personnel who had been running liver enzyme tests on blood sample from residents in a small community because of a hepatitis A outbreak—a disease easily spread by contact with an infected person.

The individual running the analytical equipment, a nonlaboratorian, had run out of what is referred to as a standard—a sample included with chemistry systems necessary for proper calibration and quality control of the equipment.

It was decided that "The machine ran just fine without it anyway because it usually read the same". And the other full- and part-time on-the-job-trained laboratory personnel using the equipment had not stated otherwise.

There was no written documentation to verify this, and no way to realize that the machine was not correctly calibrated. In the meantime, test results were interpreted, and those people whose tests did not show any signs of a diseased state went on with their daily lives, a few to jobs as food-handlers in the community's restaurants popular with the large tourist trade; others, students, were daily bussed to a large city for schooling, and many continued community to jobs outside the community.

By the time I was on-site to conduct a third survey, patients previously testing within normal limits had presented with a disease, and in the meantime had infected others. It was realized that the initial chemistry screening results were most likely invalid, and the laboratory work had since been sent to an outside laboratory.

I do not know if any loss of life occurred because of this laboratory mistake in judgment—although it easily could have in someone more susceptible to an acute illness, such as an elderly person or a small baby.

I am aware that the outbreak went on for many more weeks and hit many more people in and out of the community than would have become ill with an earlier diagnosis of the disease through accurate laboratory testing.

There were many needless days missed away from jobs and school, not to mention the very inconvenience of being ill and the effect it has had on the daily lives of the afflicted. This type of erroneous laboratory data can result in misdiagnosis, improper medical treatment, prolonged hospital stays, and has a great effect on health and health care costs.

People in the medical profession deal daily with symptoms and disease states. The symptom in physician office laboratories is the lack of properly trained personnel in most unlicensed POLs. The disease itself is caused by the lack of any comprehensive, formal, clinical laboratory training received by the vast majority of physicians, other than pathologists, while in medical school or in internship for any extended period of time.

In the CDC Oregon study, none of the physicians I surveyed in general practice had any formal laboratory training, and only forty-seven percent in family practice and thirty-three percent in internal medicine stated to having any formal training.

Yet these are the very people who go on to be the directors of their office laboratories—licensed or unlicensed. This is compounded by the claims of the user-friendly, walk-way technology equipment available in the health care marketplace, which promises to generate great amounts of money for a doctor's practice with supposed little or no need for trained personnel.

As for the conclusions of the CDC Oregon study, though there initially seemed to be some improvement in the performance of unlicensed POLs after the distribution of educational material, there is no evidence to indicate that the performance change was statistically significant or attributable to the intervention of this material.

I find the regulatory model mentioned earlier today by the ASMT representative unique and exemplary in that it provides comprehensive regulation to all laboratory testing sites, with the education and training of laboratory personnel based on the complexity of the test methodology. Thus, this regulatory model can be applied to all testing locations, including physicians' office laboratories.

It is a feasible means for effective improvements in the performance of laboratory testing and providing health care in an effective manner and at a reasonable cost.

I thank you for your consideration of the POL phenomenon which has far-reaching implications to our country's health care system in the years to come.

Senator COHEN. Thank you very much for your testimony.

Ms. Worrest, would you agree with Dr. Fischer that the Federal government really should not focus upon the level of testing? Dr. Fischer was indicating that the number of tests is really not the relevant criterion and it really should deal with the adequacy of the lab itself or the doctor's office itself. But you cannot measure adequacy by setting some sort of artificial standard those who do more than five thousand, are suddenly under regulation, and those who do less than five thousand are still exempt.

Would you agree that the standard that Congress in its wisdom has imposed is not the relevant one?

Ms. WORREST. I think that the five thousand number is irrelevant. A test is a test. Whether it is the only one done in the laboratory or is the five thousand and first test, you still should require the accuracy of that test.

Senator COHEN. So you would agree with Dr. Fischer that we should not be focusing upon the number of tests that are performed, but rather on the types of tests that are performed in physician office labs?

Ms. WORREST. Right. You might be talking about two levels here, because I heard earlier the testimony about the Pap smears. That is a different situation than what you are finding in physicians' office laboratories.

Again, giving a number to it is irrelevant. It is the accuracy of the test.

Senator COHEN. Do you agree with Dr. Fischer that we should look to voluntary standards first, those set by professional societies, before turning to Federal regulation?

Ms. WORREST. Personally, I would say that the profession has had a chance to show that they voluntarily want to do this. The regulation on the Federal level has been discussed for quite a few years now. I found that they were aware of it when I surveyed the physicians' office laboratories. They did not ask me so much was it going to come, but when was it coming.

I am concerned that they have not made better inroads into already trying to regulate themselves through some manner of proficiency testing and personnel standards in their laboratories.

It seems to me that the threat of Federal regulation should not be the motivating factor.

Senator COHEN. What about specific educational requirements or particular degree requirements; are these necessary for all POLs? Is there on-the-job training that could be conducted that would be satisfactory, or do you have to have a degree?

Ms. WORREST. A consultant with the appropriate degree in the clinical laboratory sciences would easily be and should be utilized in monthly/bimonthly overviews of quality control, test procedures and POL personnel. On the job training should not be done, mainly because of the flurry of activity that goes on in these situations, that it is almost impossible to get much of anything done and carried from one step to the final step in any given amount of time, because of all the different activities being carried out in a POL by the person(s) responsible for the laboratory testing.

I did find in these laboratories that there is a minimal licensure required for x-ray technicians, or people doing x-rays. There were very often the same people doing the laboratory testing, and they had off-the-job training in how to do a limited amount of taking x-rays.

This, I think, could be very constructive—or, depending upon the test methodology used in that POL, this same type of approach could be very successful for those people who work in the POLs doing the laboratory testing. They would at least be skilled in those test methodologies used in the POL.

Senator COHEN. Dr. Fischer, I think you used the phrase "wait three to five years and see what evolves." In other words, if more physicians do not implement the proficiency testing and don't agree to voluntarily institute these measures, then you would recommend regulation?

Dr. FISCHER. Yes. At this point, I don't think anyone knows the extent of the problem. There are a lot of anecdotes, but we really don't know the extent of the problem.

Likewise there are not enough experiments out there to know what regulation would be appropriate and able to be accomplished. So I think to start regulation at this point would be premature.

And I disagree that the professions have had a long enough time to look at this. The office lab field has really developed over the last five or ten years, and when you compare that to hospitals which, for the last thirty years have been working on this kind of issue—I think you are going to see catch-up maturity to the office lab field, and it should not take as long as it did hospital and reference labs, because the principles are very similar.

Senator COHEN. The fear of Federal regulation concentrates the mind wonderfully. What about the fear of litigation? Doctors have always been concerned about that. There seems to be a proliferation of malpractice suits in our country. We are much more litigious now than perhaps twenty or thirty years ago. Has that been a factor also, or is that a factor that should be considered?

Dr. FISCHER. It has been discussed. I don't think it is really an effective motivator, the reason for that being that there are in fact very few malpractice cases that involve laboratory testing. You have got a couple of them here this morning, but there really are very few of them. And the clinician is often named as a defendant in those cases, for a variety of reasons, so the liability is there whether you are doing the test or just ordering the test.

Senator COHEN. To the extent that it has been factored out—a physician orders a test that goes to an independent laboratory. The physician is not liable for a mistake made in the lab, should there be one, is he?

Dr. FISCHER. Physicians are named as co-defendants in many of these cases.

Senator COHEN. He may be named as a co-defendant. The success rate, I assume, is not great in suing doctors for work that is being performed by independent laboratories.

Dr. FISCHER. Well, I will give you an example. There is one case where a baby had jaundice, and the lab made a mistake on the specimen, saying the baby was not jaundiced. The baby eventually had a bad outcome.

The clinician was sued because they said, "Even though the lab told you the baby wasn't jaundiced, you should have known better."

So doctors are liable one way or the other—clinicians are liable one way or the other.

Senator COHEN. So you see no change. By having an expanded role of testing in their own office—you don't see an expanded liability beyond what it is now?

Dr. FISCHER. I think there is a little bit of an increased liability. I don't think that should be looked upon as an effective motivator to solve this problem.

Senator COHEN. In other words, look at us as the effective motivator—Senators Cohen and Levin are breathing down your necks. Therefore, we want you to participate more, take better precautions, have better training of personnel, have continuing education and so forth. That is the threat.

Dr. FISCHER. I think in the flesh here, in 1988, that is likely to be the most effective thing to get people's attention.

Senator COHEN. Thank you both very much. You both have been very helpful.

Our final panel consists of the State laboratory regulators, and our first witness is Dr. Herbert W. Dickerman, Director of the Wadsworth Center for Laboratories and Research for the New York State Department of Health. Also testifying will be Josephine Bartola, the Director of the Division of Laboratory Improvement for the State of Pennsylvania.

I did not see Senator Heinz on the floor. I think he is at another meeting right now, but hopefully, he will be back in time to hear you.

Dr. Dickerman, why don't you proceed first?

TESTIMONY OF HERBERT W. DICKERMAN, M.D., DIRECTOR, WADSWORTH CENTER FOR LABORATORIES AND RESEARCH, N.Y. STATE DEPARTMENT OF HEALTH [1]

Dr. DICKERMAN. Thank you.

Thank you for the opportunity to share in discussions on the critical issues surrounding the Federal government's role in assuring the quality of medical laboratory testing. The reliability of analyses performed by clinical laboratories in all specialties and at all service sites, including physician offices, must be assured in order to protect the health of our citizens.

As Director of the Wadsworth Center of the New York State Department of Health, which has had a long history of clinical laboratory regulation, I would like to take this opportunity to review the regulatory issues before us and to recommend action at the Federal level.

I believe there is an urgent need for stimulation of State programs, coordination of existing Federal agency resources, establishment of national minimum standards, encouragement of personnel education in laboratory specialties, and expedited enforcement and remedial action.

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[1] See p. 231 for Dr. Dickerman's prepared statement.

Nearly twenty-three years ago, New York became the first State in the Nation to initiate a certification and licensure program for clinical laboratories. Enabling legislation was the State's Laboratory Improvement Act of 1964. The Federal government used New York State's program as a model for legislation seeking to develop nationwide clinical laboratory standards—CLIA of 1967.

Since 1972, New York has remained the only State where clinical laboratories are exempt from Federal interstate inspection, because our standards are acknowledged as equal to or more stringent than Federal ones.

A detailed description of the New York State program has been provided with my written testimony.

The aim of our program is not to put laboratories out of business, but to assist them in achieving reliability of test results crucial to the diagnosis and treatment of disease.

Our governmental role is to assure the quality of information used for the care of patients. Thus, if a laboratory is deficient, it is subjected to immediate action, including remedial education. If that fails to bring about the desired changes, the laboratory's license is revoked. That is something which is quite different from anything we have heard this morning.

Many of the problems and concerns with national regulation can be traced to the multiple governmental units involved in clinical laboratory oversight. FDA, HCFA, and CDC all have clear statutory roles. Yet there is no coherent central philosophy guiding their activities.

Management by memoranda of understanding between several agencies with separate agendas does not adequately assign responsibility and accountability.

FDA is charged with approving equipment, kits, and devices for *in vitro* diagnostic use. Yet there are no provisions to assure that these tests are performed correctly or that the results are accurate.

The HCFA program, by regulating only independent laboratories which bill Medicare, leaves many facilities without oversight. As the Medicare state agency for New York, it is our experience that HCFA laboratory inspections place far too much emphasis on paper documentation of personnel qualifications and survey processing deadlines and not enough on quality assurance considerations.

A streamlined process for stopping laboratories with marginal performance is clearly called for, balancing due process with the public need for quality assurance and immediate intervention.

CDC has been forced to abandon proficiency testing of laboratories engaged in interstate commerce, leaving quality assurance to professional associations which provide voluntary testing programs with no regulatory authority or public accountability. There is no one central government entity responsible for guaranteeing quality assurance in laboratories.

CDC has no direct responsibility for the technical operation of clinical laboratories, even though it is clearly the agency with the most expertise. CDC recently proposed standards to HCFA recommending national criteria for proficiency testing in Medicare laboratories and calling for quarterly proficiency testing in all categories.

We believe that test challenges, not their frequency, are the key to assessing a laboratory's ability to perform reliably. CDC's proposed minimum acceptable score for all categories is lower than that employed by our program in comparable categories.

More disturbing from a regulatory point of view is that the failing score proposed would usually yield, in our view, too broad a range of acceptable results. Applying these guidelines, only one percent of examined laboratories would face failure. Our experience indicates more rigorous standards are appropriate. Yet another weakness of the CDC proposal is the exemption from proficiency testing of Pap smear screening as well as other vital categories.

HCFA has chosen to delegate much of its regulatory responsibilities to voluntary peer review programs such as those administered by CAP or the Joint Commission. These programs are not regulatory, nor are they designed to be. The scheme lacks the crucial ingredient of public accountability—the assurance that laboratory services offered to the public are of the highest quality, and that those laboratories not complying with this standard will not be permitted to operate.

Delegation of authority to peer review organizations is a clear abdication of the regulatory role.

My written testimony details specific concerns with the CAP and JC programs in contrast to New York's.

Another concern is the lack of quality assurance in laboratories located in physicians' offices and other service sites. While I understand that by January of 1989 HCFA will require some oversight of physician office laboratories performing five thousand or more tests, I have yet to see the regulatory language for this requirement. However, if the criteria is simply five thousand tests billed to Medicare, POLs serving young women and children will continue to go unregulated, and there is no available mechanism to identify these offices requiring regulation.

Of interest is the growing phenomenon of reading Pap smear results in physician offices. Granted, this involves primarily gynecologists in a general medical setting. The Wadsworth Center, at present prohibited by statute from regulating testing in POLs, is proposing legislation calling for a survey to determine the nature and extent of Pap smear testing in New York State in POLs. While we are concerned with POL testing overall, the area of Pap smears is critical at this time. If some certified laboratories under a certain level of regulation are missing cervical cancer, what is happening in the doctor's office.

Many primary ambulatory care clinics and rural health centers, which must provide certain tests to receive Federal approval, are under no regulatory oversight at all and are not required to participate either in State or HCFA programs. This issue should be addressed forthwith.

We can only ask—what is the quality of testing outside our state? Other deficiencies in Federal regulation include employee drug testing, occupational safety and health, WIC program eligibility criteria, and testing for insurance underwriting purposes.

Regardless of the setting of the test, we believe that the entire population is entitled to quality assurance in laboratory testing. The current regulatory patchwork clearly does not further this objective.

Our recommendations for Federal action: New York State believes that the regulation of laboratories belongs at the state level, for government closest to the regulated parties is most effective. The Federal government must establish national minimum standards for laboratory testing and take steps to stimulate state regulation, an original goal of CLIA.

All testing of human specimens, whether in hospitals, clinics, POLs, or for occupational health, employee drug testing or insurance underwriting purposes, must be regulated.

Through grants to the States, encouragement should be provided for the development of laboratory evaluation programs, with ongoing support past the initial set-up based on the assessment of laboratory fees, as it is done in the State of New York.

Senator COHEN. Dr. Dickerman, could I interrupt you for a moment? How would we pass legislation without first having established guidelines and goals? You mentioned giving grants to states and localities to develop laboratory regulations. How do we pass a law, or should we pass a law, mandating something when we don't know what the standards ought to be at this point?

Dr. DICKERMAN. I would suggest that there are minimum standards that we could arrive at in quality control, in quality assessment, proficiency testing, for instance, that even a meeting of the minds between CDC and CAP and ourselves would come up with a bare-bones program to begin with.

What I think is most important is that there have to be grants to the states to set up programs in ongoing laboratories, with trained personnel who are also doing service work so they have expertise in state-of-the-art, therefore can be in the role of inspector, not in a voluntary manner. There is quite a difference between being a voluntary inspector and being a state inspector.

So I think at that point the states have to assess the industry. And I think the ongoing program can be supported by a laboratory fee.

Senator COHEN. Why has New York exempted POLs from its regulation?

Dr. DICKERMAN. I don't really know. It is not an oversight. We have had initiatives. I just can't speak to it. We have certainly wanted to get into the area, and we are getting into the area, but I would say belatedly.

We did want to see other States' experience, and there was some experience in California which certainly motivated us on the basis of laboratory results that were obtained there. I don't know. I haven't got a good answer.

Senator COHEN. Could you tell us why New York does not recognize the Joint Commission or the CAP accreditation instead of its own State program?

Dr. DICKERMAN. I would like to say it is philosophy, but it is more than philosophy. We regulate, we enforce. We try to remediate, we try to educate; we re-test, we inspect. We issue deficiency statements, as most inspectors do, which lead to corrections. But there comes a bottom line, and that bottom line may be anywhere between one to five percent of our licensed laboratories. And there is no intent to remediate. There is no intent on that licensed laboratory's part to correct. And at that point in time, either they are completely operational or they are really being fraudulent, and at that point in time, enforcement is the only way that it can be handled.

I might add—and we have heard this before—I think there is a little statistic which I would like to give you. In any given year, ten to fifteen percent of all the laboratories will fail some clinical testing category, but the numbers are improving. In 1981, forty-six percent of all licensed laboratories failed the proficiency test in mycology, fungus studies. Today only three percent fail. In 1971, forty-seven percent of all laboratories failed the initial cytology proficiency exam; today, about twenty percent fail the first test, and after remediation, virtually all laboratories that took the re-test were able to pass.

And I do not mean to leave you with the impression that proficiency testing is anything more than what Dr. Barr said. It is testing the best possible situation. This is not a satisfactory method. We are going to try to do blind testing. We are under an imperative from our Commissioner to devise methods which are really quite complex, and have legal implications. But that we the only way you could really say that you are testing the real laboratory. And we are going to focus on the cytotechnologists, not only on the total performance of the cytopathology lab.

But what we do is to have a temperature taken of the best that that laboratory can do. In the area of cytology, however, I think we do better, because we do go to each tech within the lab.

Senator Cohen. You indicated in your printed testimony that the Joint Commission has never revoked approval of a hospital based on deficiencies in the hospital's lab. Is there evidence to suggest that any hospitals should have had their accreditation removed?

Dr. Dickerman. Oh, yes, there have been hospitals, that in certain categories, couldn't do a hematocrit. Now, that is awful. This is an emergency room situation. A bleeding patient comes in, and they cannot even do a hematocrit. And we have to say, "No, you can't."

And they say, "But we have an emergency."

I say at that point, "You cannot do it because you don't show any proficiency in doing it. It doesn't make any sense. You will have to get a neighboring hospital or somebody else to take over that particular service in some way or another."

That may sound arbitrary, bureaucratic, and everything else, but unless that is done in particular categories, you are not going to change anything.

Senator Cohen. In proficiency testing for microbiology, my understanding is that the CDC has a proposed minimum of seventy percent. Do you think that is sufficent?

Dr. Dickerman. Well, our objection to CDC is not in that area so much as what we hear, that they may go to three standard deviations in their chemical ranges, which we think is too wide a range. It is not narrow enough to give complete accuracy within stated tests.

Senator Cohen. So you don't have a problem with the seventy percent?

Dr. Dickerman. No. What we do have a problem with is the formalism of the proposal's structures and I think it is being formalized along CAP lines. They go for four proficiency tests a year. Well, we don't happen to do that in some fields. For instance, in cytology, we only have biennial exams; in other categories like cytogenetics, annual exams; in others, semi-annual. And we don't think it is a question of frequency. This becomes a very, very important problem to us in New York, because under CLIA air licenses have been exempt. Our laboratories have not had to go to CAP. And if we don't restructure our program to four proficiency tests a year—rather than the total number of analytes, or frequency of challenges, which we exceed—to get into bureaucratic formulas just to adjust to another particular group's way of handling this—no, we don't see that at all, and we are quite adamant about that; we don't accept it.

Senator Cohen. You have said we have to do something at the Federal level to those labs who have a marginal level of performance. Is it your judgment that HCFA doesn't have the authority or the will to do this?

Dr. Dickerman. Oh, they have the authority, but they are looking at process; they are not looking at product. They are looking at whether they have the right paper work. There is a question here: I do this. And you put that on a paper. That is not testing anybody's realities. That is just saying yes, the paper is there. We are asking for on-site inspections, hand-carried specimens, proficiency testing. And if a laboratory does not perform, there should be an immediate way of stopping that service.

The problem is that when you deal with HCFA, if you don't have the paper work, that can stop your service. But to get the certification of a laboratory on the basis of actual performance is a much more arduous duty and task.

Senator Cohen. Why don't you complete your statement and then we will move on to Ms. Bartola.

Dr. Dickerman. While clinical laboratories must be protected against arbitrary and capricious enforcement activities, an expedited legal process—just what we are referring to now—to halt patient testing in instances of documented deficiencies in quality or proficiency, is essential to safeguard the patients' health.

Another important area is a national direct billing law, similar to the one that we have in New York, which requires that the laboratories bill the patient or the insurance carrier rather than the physician. This would eliminate incentives to choose laboratories based on cost considerations and would assure that the public knows where tests are actually performed.

One of the most critical areas in this context is the shortage of qualified medical technologists and cytotechnologists—absolutely essential for quality laboratory services.

Health manpower development funds for educational programs are desperately needed, and action must be taken to improve the status, advancement and wages of these laboratory personnel to keep them in the field.

In closing, I believe we must assure the validity and reliability of laboratory testing services, whether in the laboratory, hospital, clinic or office, to guarantee protection of the public health.

Thank you.

Senator COHEN. Thank you very much, Dr. Dickerman.

Dr. Dickerman, we had earlier testimony that physicians were not engaged in reading Pap smears in their offices. And as I listened to your testimony, you indicated there was——

Dr. DICKERMAN. I think that is generally so for general practitioners, but I think there are gynecologists—in fact, we have case evidence of gynecologists who have technicians working in their offices, not under the supervision of a pathologist, but directly for the gynecologist. That is what we are talking about in office testing. It is much more restrictive. There is no intervening cytopathologist. And we think that is a definite necessity. There has to be somebody who can provide pathological backup to the cytotechnologist.

Senator COHEN. Thank you very much.

Ms. Bartola.

TESTIMONY OF JOSEPHINE BARTOLA, J.D., DIRECTOR, DIVISION OF LABORATORY IMPROVEMENT, BUREAU OF LABORATORIES, PENNSYLVANIA STATE DEPARTMENT OF HEALTH [1]

Dr. BARTOLA. Thank you, Senator Cohen, for the opportunity to appear today to share with you Pennsylvania's efforts in attempting to ensure quality laboratory services for its citizens.

Pennsylvania has a long legislative history of regulating clinical laboratories beginning with the Clinical Laboratory Act of 1951, when only non-physicians operating laboratories were required to obtain a license. However, in 1972 the Act was amended to remove all exemptions except for Federal teaching and research laboratories. Today, all clinical testing performed in Pennsylvania on Pennsylvania residents is subject to licensure no matter where it is performed.

Pennsylvania licensure requirements for hospital and independent laboratories are essentially equivalent to the Federal standards developed for Medicare certification and interstate licensure. These include specific academic credentials and experience at the director, supervisor and technologist levels; an annual on-site survey; documented quality control systems; acceptable participation in an approved proficiency testing program; current procedure manuals and appropriate recordkeeping.

I might add that our office does the Medicare certification and interstate functions for the Federal government.

In attempting to apply existing regulations to the physician office laboratories back in 1972, the Department encountered considerable difficulties. Most of the POLs simply could not qualify for licensure. Most of the physicians and the personnel performing the testing lacked formal laboratory training, and in many instances were not aware of good laboratory practices.

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[1] See p. 248 for Dr. Bartola's prepared statement.

There were, of course, exceptions. We have some fine exceptions in the State, but they were in the minority.

Senator **Cohen**. That was in 1971?

Dr. **Bartola**. This was back in 1972, when we were first considering regulation.

Another factor we had to consider in developing regulations for our POL's under the new law was the enormous cost of applying the full licensure requirements to the thousands of POLs in our State. We knew we simply could not afford it.

Senator **Cohen**. So did you tailor the licensing requirements to conform to the practice in the POLs, or did you ask the POLs to come up to the higher standard of hospitals and independent labs?

Dr. **Bartola**. I have described in my formal testimony what we did—briefly, we surveyed the State to determine exactly what testing was done because, as you know, in the physician office laboratories, you have a wide range of testing performed, anything from a few dipsticks to a full service laboratory. We felt at the time that even if we obtained the funds, which was not likely, it would not be a prudent expenditure of public funds to do an on-site survey of a physician's office laboratory that is doing only a few tests.

We had extensive deliberations with representatives from our Pennsylvania Medical Society, and our Statutory Advisory Committee which is made up of pathologists and other laboratory personnel. Together, we developed our current three-level regulatory system for physician office laboratories, and these have been implemented aggressively since 1980.

The tests included at each level are based on the level of complexity and the need for independent judgment. The levels and methods are fully described in my prepared testimony.

We currently have six thousand one hundred seventy-four laboratories in our program. Three hundred of them are hospital labs; two hundred seventy-four are independent laboratories; fifty-six hundred are POLs. And of those fifty-six hundred, three thousand one hundred fifty of them are performing at Level 1, which means they are doing simple qualitative-type tests for the most part, for only quality control requirements are imposed at this level.

At the second level we have fourteen hundred POLs. We require quality control and proficiency testing at the second level. They are doing a number of more complex tests in addition to the tests permitted at Level 1.

At the third level, we have one thousand fifty POLs, and these are subject to full licensure as I have described in the prepared testimony.

All the laboratories in our program except the Level 1 POLs are required to participate in an approved proficiency testing program, and all results are monitored and action taken as necessary. The approved programs, the number and frequency of challenges, the grading criteria and the consequences of unsuccessful participation are also fully described in the prepared testimony.

The Pennsylvania statute permits revocation of a license for all violations of the regulations which may jeopardize the integrity and reliability of the test results.

There is no simple formula for ensuring quality assurance and accountability in the laboratory. The very nature of laboratory work, with the number of variables that are operating in any given test and the thousands, millions, that are done daily, requires daily, consistent, internal quality control and periodic external monitoring. It requires the consistent efforts of everyone involved in the process, not only the Federal Government, but I believe the States have to take more responsibility for monitoring their laboratories, as well as professional organizations, the manufacturers of instruments and reagents and we must be able to rely on the intellectual integrity of the individuals responsible for the testing themselves.

What we are attempting to do in Pennsylvania is to create the environment which will encourage our laboratories to consistently adhere to good laboratory practices. We do this in a number of ways in addition to the regulatory process.

In addition to our Statutory Advisory Committee, which deals with policy issues, we have established technical committees in clinical chemistry and microbiology made up of technical professionals from our licensed laboratories who meet at regular intervals to review the regulatory requirements for relevance and state-of-the-art, because the technology continues to change, and we have go to change with it.

These members are rotated to permit wide representation and a fresh infusion of ideas. We believe that permitting our laboratory community to be part of the process encourages compliance.

We have also encouraged a closer relationship with manufacturers, who frequently address the committees regarding their products. We think this is important because in monitoring proficiency testing results, we have identified problems with the products from time to time. We bring them the attention of the manufacturer and sometimes are able to effect changes.

We articulate the standards and try to provide a rationale for the standards, because I think if the laboratories know why they are being required to do something, there is a better chance of compliance.

Senator Cohen. Do you have a different standard for physicians' labs than you do for hospitals or independent labs?

Dr. Bartola. At Level 1 and Level 2—the quality control requirements are not different, only the degree of monitoring differs. It is based on the complexity of the work done. We would agree with Dr. Barr and their recommendation, that the standards should be designed for the complexity of the work that is performed.

You need not regulate a physician's office doing simple tests the way you do a large laboratory such as Smith Kline-Bro. Service or Metpath; it is simply not necessary.

We do consistent monitoring of all our countries for both performance and compliance, and we do withdraw the license to perform when the standards are violated.

Therefore, since we know that periodic monitoring by State and Federal regulators and the private programs has been fragmented and inconsistent, the Federal Government could make a substantial beginning toward rectifying this situation by establishing national standards of performance for all laboratory testing no matter where it is performed.

Standards should be based on the level of complexity of the testing performed rather than by the volume of tests done. Many POLs performing less than five thousand tests a year are performing complex tests which should be regulated, and at the same time, you might find a physician who is doing more than five thousand dipstick urines, and you certainly do not want to apply regulations at that level of testing.

We would also like to see a national proficiency testing program designed and required of all laboratories commensurate with the level of work performed. Acceptable grading criteria should be established, and uniform sanctions applied. We have many of the same problems with the CDC proficiency testing program proposed which Dr. Dickerman has mentioned. We think it is a good beginning, but in addition to Dr. Dickerman's criticisms, we believe the standardization of the matrix of the specimens should be addressed.

The Federal Government should assist the States perhaps through grants, as Dr. Dickerman has suggested, in developing training programs, particularly for the special needs of physician office laboratories. The nature of the office practice does not allow for staff to leave the office to attend outside workshops to acquire the necessary skills.

Senator **Cohen**. What sort of training would you recommend?

Dr. **Bartola**. What we are doing in our State is developing some training aids that they can use in-house. We have designed a good procedure manual which is to be distributed soon. We send them videocassettes describing various procedures and techniques of good laboratory practice. Many POLs are taking advantage of these. Aids such as videocassettes can be very useful, and they can be used right in the office.

I think we have to develop training programs that they can utilize in their offices because of the difficulty of getting them out to training programs.

Senator **Cohen**. Do you agree with the proposition that much of the information we have today is anecdotal, and we need a bit more time to validate the nature and the severity of the problems that are encountered?

Dr. **Bartola**. Well, I have a great deal of respect for Dr. Fischer, and if all the physicians operating laboratories were of his caliber, we would have nothing to worry about; we wouldn't need to be here today.

However, I believe we need intervention now. We have been in hundreds of laboratories already, and the basic need is there.

I would not opt to wait. I think national standards should be established and implemented as soon as possible.

Senator **Cohen**. Dr. Dickerman, you were nodding your agreement to that?

Dr. **Dickerman**. Well, I was just thinking about your asking me before why haven't we gotten into it. Well, it is only within the last few years that it has become an immensely important part of the total laboratory situation. I gather from what I read in the trade journals that some fifty percent of all tests will soon be done in POLs. We are not talking about four or five years ago when it was one percent, five percent. We are getting into big numbers now.

Dr. **Bartola**. I would like to point out another issue we have noted since DRGs. A lot of pre-admission and post-testing is done in the physician office laboratories now and I have received numerous complaints from hospitals that are reluctant to accept results from POL's that are not licensed because they have not been required to meet any minimum standards. Of course, in our State, we have identified them and we will soon have all of the POL's under licensure. That has not always been true, however, and the hospitals have been very reluctant and often did not accept results from unlicensed POL's.

So I guess the consequence was that they repeated the tests and it just added to the cost. So I really think that government intervention is essential now because voluntarism has not worked. Some sanctions are a necessary part of any effective improvement program.

Thank you.

Senator **Cohen**. Dr. Bartola, thank you very much. Just a brief question. You mentioned the inconsistencies in regulations. What sort of inconsistencies are you referring to?

Is there an inconsistency between the Federal regulations and those that you have adopted in the State of Pennsylvania itself?

Dr. **Bartola**. Well, I am talking generally. In Pennsylvania we have a program that we apply to all our laboratories, whether they be a hospital, an independent laboratory, or a physician office laboratory, consistent with our protocol.

Senator **Cohen**. Is there a problem from Pennsylvania's point of view with what is an inconsistency in the application of the Federal law in Pennsylvania and your own laws?

Dr. **Bartola**. Well, if you mean with the Federal approach, yes, of course, because the JCAH which has deemed status is on a three-year on-site survey schedule for hospitals, the CAP is on a two-year cycle, while the independent laboratories are surveyed every year, and the physician offices not at all. This has created problems for us because we have tried to utilize the survey results of the JCAH and CAP but this erratic schedule does not permit adequate monitoring. We must perform the surveys in the intervening years to expect compliance with State and Federal laws.

Yes, this fragmented approach is a problem even within our State.

Senator **Cohen**. What about removing personnel standards for those who are below the director of the lab? Do you support those proposals?

Dr. **Bartola**. I think we would be reluctant to remove standards from the supervisory level, because I believe, and there is an old study which is still valid, which shows that the strength of the laboratory lies at the supervisory level. This has been our experience also so I would be reluctant to remove personnel standards at the supervisory level.

We have found that with some simple tests performed in the physician office laboratory, with adequate training—and I have to emphasize the training aspect—you can teach nonlaboratory personnel to do some of these simple tests well with the good technology available today. But this is limited to quantitative-type testing.

When you get into subjective type testing such as microbiology, which requires more independent judgment, our studies have found that some formal laboratory training is necessary.

Dr. **Dickerman**. We take a slightly different viewpoint. The whole responsibility for a laboratory lies in the certificate of qualification holder. That is the senior professional within that laboratory.

We do obviously have to make sure that the records and credentials of people working there as medical technologists or any other particular technologists reflect adequate training. But the responsibility is on the person holding what we call certificate of qualification a "CQ". The loss of the CQ can be a very traumatic experience.

I would like, if I may have an opportunity, to make some small comments. One, I think it is very important that one agency at the Federal level have responsibility in the laboratory regulation area. From our standpoint, it should be the CDC.

The second point concerns the adequacy of cytology proficiency testing. Our program has been in existence from 1967, and I think we have a reliable program which is based on biopsy-proven material and concurrence of three reference pathologists, and very good consistency between slide packages.

So I don't think, as we have heard from the CDC—unfortunately—and from HCFA, that cytology is an area that cannot be directly proficiency tested. I would like to put that on the record.

Dr. **Bartola**. I would like to agree with him. Dr. Collins up in New York has a fine program, and Pennsylvania is in the process of developing a program on her model. It is possible. It is not easy, and it is expensive, at least the initial outlay, but it appears to be a very effective program.

Senator **Cohen**. Well, we are limited by time today. I want to thank both of you for your testimony.

I would in addition to that express my appreciation for the work that is being done by Pennsylvania and New York. You really are setting a standard to which the rest of the States ought to look for some guidance, and hopefully you will be able to set some standards for us, too.

Thank you very much.

The Subcommittee stands adjourned.

[Whereupon, at 1:30 p.m., the Subcommittee was adjourned, to reconvene Thursday, March 24, 1988.]

HEALTH CARE FINANCING ADMINISTRATION'S MANAGEMENT OF MEDICAL LABORATORIES

THURSDAY, MARCH 24, 1988

U.S. SENATE,
SUBCOMMITTEE ON OVERSIGHT OF
GOVERNMENT MANAGEMENT,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:33 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Carl Levin, Chairman of the Subcommittee, presiding.

Present: Senators Levin, Cohen, Heinz, and Roth.

Staff present: Linda J. Gustitus, Staff Director and Chief Counsel; Allison C. Giles, Professional Staff Member; Mary Berry Gerwin, Minority Staff Director and Chief Counsel; Kim Corthell, Professional Staff Member; Sharon Ward, Professional Staff Member; Frankie de Vergie, Chief Clerk; and Tania Chadbourne, Intern.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Good morning, everybody. Today is the second day of hearings that this Subcommittee is holding on medical laboratory testing.

We are specifically examining whether the Federal Government and the Health Care Financing Administration, HCFA in particular, is fulfilling its obligation to ensure maximum safety and accuracy in the approximately 13,000 laboratories under Federal regulation.

We are also looking at the 80,000 to 100,000 laboratories which escape Federal regulation entirely, some of which do come under limited State regulation.

Yesterday, we heard very sobering testimony about the tragic consequences of some laboratory errors. Mr. Bob Johnson testified about a lab worker who misread his wife's Pap smears two years in a row, with the result that his wife's cervical cancer escaped detection and treatment until it was too late.

In the case of Kathy and David Astor, the lab worker made a simple mathematical error. The Astors did not find out until too late that they are both carriers of the Tay-Sachs gene, and their young daughter Abigail now has the fatal Tay-Sachs disease.

We also heard from several associations representing lab technologists and directors about lab workers who are pressured to review several hundred Pap smears a day; about the shortage of qualified lab personnel; about inadequate proficiency testing, which does not adequately measure a lab's typical performance; about lax enforcement of appropriate standards; and about a range of serious problems in physician office labs, which, as I've indicated, are largely unregulated.

The numerous questions raised yesterday demonstrate that there are serious gaps and deficiencies in the Federal regulation of laboratories.

Among our witnesses today is the Health Care Financing Administration, HCFA, which has primary responsibility for the Federal regulation of labs.

In addition, several private organizations, namely, the Joint Commission and the College of American Pathologists, which also have inspection and accrediting authority over labs, will be testifying.

We need to discuss with these witnesses how to solve some of the troubling problems which have been raised.

We have an obligation to reduce as much as possible the rate of significant lab testing errors. I hope these witnesses today will help us explore how we can reasonably an effectively accomplish that goal.

I next turn to Senator Bill Cohen who, as I indicated yesterday, has a longstanding interest in this subject, who has requested and initiated these hearings, and who is really responsible for the progress which already has been made, and which we hope will be made in the future on this issue.

OPENING STATEMENT OF SENATOR COHEN

Senator **Cohen**. Thanks very much, Mr. Chairman.

Without reiterating what you have said about the disturbing testimony we heard yesterday, it really is rather dramatic to hear about excessive workloads, piecemeal pay for screening Pap smears, a factory type of mentality at work, and laboratory workers analyzing slides with little or no supervision. These seem to be more the norm than the exception, and that ought to be of great concern to everybody in this country.

Some of our witnesses yesterday criticized our current Federal regulatory system that governs labs. We heard testimony that the inspection and enforcement practices of the Federal Government and the States are uneven and at times superficial; that HCFA has not been aggressive in its enforcement against labs.

We also heard about the private entities that now enjoy so-called deemed status, Medicare and the Clinical Laboratory Improvement Act, on the grounds that their standards and inspection practices are inadequate to ensure true quality, and because they adopt an educational rather than an enforcement or regulatory approach in reviewing lab quality.

Our own investigations revealed very definite weaknesses in the Federal Government's lab regulation program. We have found, just to give you an example, that the current regulatory scheme is an uneven one, with multiple types and levels of enforcement. Different standards and enforcement mechanisms exist for labs operating across State lines and for labs that are Medicare reimbursed.

In some cases labs can be terminated under one program, and yet continue to receive Federal reimbursement under another. So with one hand we are saying that these labs are not qualified to perform these types of tests; but the other hand is nonetheless paying over the money. That to me is an outrageous situation.

We have determined that the Federal Government does not have a national system under which it decides to flunk or pass a lab for its performance on a particular test. In many cases the government now lacks the tools it needs to take action against labs that do perform poorly on tests.

Without strong enforcement and oversight mechanisms in place, we can never be sure that poor lab performers are being removed from the system. We also cannot be sure that we are getting what we are paying for with Medicare and Medicaid dollars. Those dollars pay for almost 40 percent of the lab tests that are performed in this country. Even more importantly, we cannot be sure that lives and health of our citizens are being protected.

Today we will address these issues with the agency that is charged with enforcing the Federal lab program, the Health Care Financing Administration, called HCFA, to probe what is being done to improve laboratory enforcement and oversight.

We will also hear from the Centers for Disease Control which shares responsibility with HCFA in promoting lab quality. And we will hear from two of the private sector organizations which have deemed status under CLIA, the Clinical Laboratory Improvement Act, or Medicare, namely, the College of American Pathologists, and the Joint Commission on Accreditation of Healthcare Organizations, as well as several representatives from laboratories and medical professional societies.

Mr. Chairman, I want to thank you for your willingness, indeed eagerness, in holding these hearings. You of all the people I have worked with in the Senate have been perhaps the most enthusiastic about working on a bipartisan basis to deal with issues that transcend any party lines, and this is certainly one of those issues.

Senator LEVIN. Thank you very much, Senator Cohen.

Senator Pryor, who could not be with us today, has a statement that he would like placed into the record and we will do so at this time.

[Senator Pryor's statement follows:]

OPENING STATEMENT OF SENATOR PRYOR

Mr. Chairman and Senator Cohen, I would like to thank you for holding these two days of hearings on this very important subject of the regulation and oversight of medical laboratories. I understand that the subcommittee heard very moving testimony yesterday from two people who had personal experience with errors in laboratory testing.

It appears that changing laboratory technology and the growing number of physician operated labs has outstripped current federal regulations. Quality assurance has been left much to the labs and private accreditation organizations. It is beginning to appear that this type of self-policing may no longer be a feasible plan of action. For example, one of the witnesses yesterday stated that anywhere from one-half to two-thirds of all laboratories that screen PAP smears require their technicians to process many more slides than the recommended safe, reliable standard. I applaud your efforts to ensure that problems in this area, which appear to be on the increase, are recognized and corrected.

Along with my colleagues on the Finance Committee, I have had to make some difficult Medicare votes in recent years with the goals of curbing health care inflation and dedicit reduction in mind. Medicare payment reductions have put the squeeze on providers to the point where some have begun to cut corners. We in Congress have found out the hard way that, along with our commitment to balance the national budget, we have a corresponding responsibility to ensure that health care services paid for by our government are reliable, quality services, performed by able, trained practitioners. Quality health services are a right and make sound fiscal sense for the government as a purchaser.

I don't have all the answers for improving the quality of laboratory tests. However, in recent years we have taken some steps to help ensure quality health care. Hospital services and labs have come under increased scrutiny, as have nursing homes and home health providers. Most recently, as part of the latest reconciliation legislation, we required that by 1990 all doctors' offices performing more than 5,000 lab tests per year must meet the requirements of the Clinical Laboratories Improvement Act.

In addition, the Senate catastrophic illness package, which is currently in conference, contains a provision which prohibits the Secretary of HHS from administering proficiency examinations for individuals wanting to be certified as medical technicians. This prohibition will ensure that technicians cannot "test out" of the necessary years of training. Both of these actions are an effort by the Congress to better monitor the quality of laboratory tests and services. It appears that much more could be done in this area. However, I am well aware that any measure must be weighed against the current critical shortage of workers.

I thank you again for holding these hearings, Mr. Chairman and Senator Cohen and I look forward to reviewing the testimony of today's witnesses.

Senator LEVIN. We now call upon our first panel: Louis B. Hays, who is the Associate Administrator for Operations of HCFA, and Dr. Paul J. Wiesner, who is the Director of Training and Laboratory Program Office of the Centers for Disease Control.

Mr. Hays and Dr. Wiesner. Mr. Hays, do you want to start off? We would appreciate your summarizing your testimony so we will have more time for questions.

I will say that to all witnesses. Please proceed.

TESTIMONY OF LOUIS B. HAYS, ASSOCIATE ADMINISTRATOR FOR OPERATIONS, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. HAYS. Certainly, Mr. Chairman, and I would ask that my full statement be made part of the record.[1]

Senator LEVIN. It will be.

Mr. HAYS. Mr. Chairman, I welcome the opportunity to discuss our efforts to assure that laboratories meet high quality standards of performance.

While we believe that the overall quality of laboratory performance is acceptable, we recognize that there is a growing concern on the part of Congress and the public about the quality and accuracy of laboratory testing.

We certainly share that concern, and have been working for over a year on this difficult problem.

I am pleased to report that we will shortly propose comprehensive laboratory, regulatory reform, which should result in further enhancement of quality and accuracy of laboratory testing.

Let me preface my remarks with a brief background on the regulation of labs. There are two major Federal programs which regulate laboratories, and both are administered by the Health Care Financing Administration.

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[1] See p. 268.

The first is the Medicare program, which covers both hospital laboratories and independent laboratories. By meeting Medicare's conditions of participation, laboratories are certified to receive payment for services provided to Medicare or Medicaid beneficiaries.

The second program resulted from the Clinical Laboratory Improvement Act of 1967, commonly referred to as CLIA. Regulations under CLIA apply to laboratories performing tests on specimens in interstate commerce.

Responsibility for administration of the CLIA program was transferred from the Centers for Disease Control to HCFA in 1979 to reduce duplicative activities in ensuring that clinical labs meet quality standards.

This action effectively consolidated the regulation of Medicare and CLIA laboratories within a single agency, making in our view the creation of a separate Office of Clinical Laboratories unnecessary.

There are over 12,000 labs participating in Medicare and Medicaid. Of these, about 4,500 are independent laboratories, and 6,600 are in hospitals.

There are over 1,500 laboratories licensed under CLIA, of which over 1,300 are also Medicare certified.

An additional 519 labs perform interstate testing but are exempt under law from CLIA regulation by accreditation by the College of American Pathologists, or licensure by the State of New York.

The primary mechanism we use for ensuring that laboratories meet quality standards is the Medicare survey and certification process.

State agencies, usually health departments, have agreements with us to survey laboratories' ongoing compliance with our regulatory conditions of participation.

The State agencies also review CLIA labs for compliance with standards that are comparable to those for Medicare laboratories.

Hospital laboratories accredited by the Joint Commission or the American Osteopathic Association are deemed, by law, to meet quality standards comparable to Medicare.

This means that the JCAHO and AOA are responsible for the timing and manner of surveying accredited hospital laboratories.

State agencies perform surveys of accredited hospitals to validate that these hospitals continue to meet quality standards. Generally the validation surveys show overall agreement with the findings of the accrediting organizations.

Similarly, Federal surveyors perform monitoring inspections to verify that State agencies are enforcing Federal requirements. We find a 98 percent correlation with State findings.

There are seven major conditions of participation that Medicare labs must meet. These include compliance with relevant State and local laws; qualifications for the laboratory director; standards for the supervision of lab testing; participation in a proficiency testing program; qualifications for technical personnel; management requirements; and an acceptable quality control program.

One of the most important conditions of participation that has recently received a great deal of attention is proficiency testing.

Both Medicare and CLIA require that laboratories participate in an approved program of proficiency testing. In some instances

States conduct proficiency testing programs. Other approved programs are conducted by approved organizations such as the College of American Pathologists and the American Association of Bioanalysts.

Generally, proficiency testing is conducted on a quarterly basis. Medicare considers three consecutive or three out of four unsuccessful proficiency testing performances to constitute the basis for terminating payment for tests in a specialty or subspecialty area.

Reinstatement of payment cannot be considered until successful performance has been achieved for two consecutive quarters of proficiency testing.

A problem with proficiency testing programs is that they vary broadly in testing criteria and in grading of test results. Moreover, at this time, there are not yet uniform or minimally acceptable Federal standards for proficiency testing programs.

Finally, there are some subspecialty areas where national proficiency testing programs do not yet exist, most notably in the area of cytology.

Before I describe our initiatives to increase our emphasis on quality in laboratories, I would like to place them in the context of the changing nature of the laboratory industry.

Advancing technologies have led to the automation of laboratory testing, resulting in the capacity simultaneously to run large numbers of tests with rapid turn-around times.

The organization and ownership of labs have also changed as a result of advancing technologies. Once primarily nonprofit and hospital-based, the laboratory industry has become one of profit-making, independent and large commercial ventures.

During this evolution, labs began competing for business by offering low prices to physicians, discounts for volumes, and shorter turn-around times.

It is within this context that we have concluded that regulatory reform for laboratories is necessary. By the end of April, next month, we expect to propose comprehensive regulations which will enhance the three fundamental components that determine the quality of laboratory performance: proficiency testing, personnel qualifications, and quality assurance in laboratories.

Senator COHEN. Would that include cytology?

Mr. HAYS. We very much hope and expect that it will. I will be pleased to discuss that in greater detail.

In general the regulations will improve outcome measures of performance; include national criteria for uniform proficiency testing; and assure that personnel requirements in the regulations reflect the state of the art in laboratory science; and finally, require quality control requirements that are appropriate for the new technologies and methodologies used in labs today.

Because of the lack of consistency in proficiency testing programs, we asked the CDC to develop a uniform proficiency testing program to be used as a national standard in evaluating the performance of Medicare and CLIA laboratories.

Last December CDC submitted a proposal for a national uniform proficiency testing program, which we are considering as part of our proposed regulation.

Personnel requirements are also an important basis for assuring quality laboratory testing. Our proposed regulations will also place greater emphasis on determining whether the responsibilities and duties of lab personnel are being successfully met through assessments of outcomes of performance.

There is, certainly, continuing public concern about the accuracy of cytology testing. We are sensitive to the attention that is being given to Pap screening. We are evaluating all options to help improve the accuracy of cytological testing through measures such as proficiency testing; standards for training and qualifications of cyto-technologists; and internal quality control procedures and quality assurance measures to be applied by the labs themselves.

We recognize that the accuracy of cytological testing remains an extremely complex health care issue, and we are working to ensure that any regulatory requirement or standard will be based on careful scientific assessment.

To assist us in surveying the quality of cytology testing, we plan to award a contract in the near future which will give us the capability of performing specialized reviews of cytology testing.

The contractor will review laboratory procedures and examine slides to determine the accuracy of test results. Findings will be reported to us for appropriate action on identified problems.

Before closing, I would like to mention the topic of physician-office laboratories. As you know, Congress has mandated a study of these labs to determine appropriate standards to protect the health and safety of patients.

The report, which will be released soon, will address such factors as the scope, type and complexity of testing in physician office labs.

We hope that the report will provoke debate and the emergence of sound policy options that will assist us in developing regulations as required by OBRA '87 for high volume physician-office labs for implementation on January 1, 1990.

In conclusion, let me reinforce our commitment to ensuring quality laboratory services, not only for Medicare and Medicaid beneficiaries, but for all of our Nation's citizens.

We recognize that the rapidly changing clinical laboratory environment requires updated, reliable quality measures to assure the adequacy and accuracy of test results.

We want to move quickly to put these measures into place, and welcome your advice, and the continued assistance of laboratory professionals in developing these reforms.

Thank you very much.

Senator **Levin**. Thank you very much, Mr. Hays.

Let me ask other colleagues who have joined us now whether they might have an opening statement, whether Senator Heinz or Senator Roth have opening statements.

Senator **Heinz**. No opening statement, Mr. Chairman.

Senator **Levin**. Senator Roth?

Senator **Roth**. Mr. Chairman, I do have an opening statement. But rather than take the time of the Subcommittee, I would ask to incorporate it in the record.

Senator **Levin**. It will be incorporated into the record.

[The opening statement of Senator Roth follows:]

OPENING STATEMENT OF SENATOR ROTH

Yesterday, this Subcommittee heard compelling testimony from witnesses who, due to erroneous clinical laboratory test results, suffered personal losses that can only be described as tragic in nature. Lab tests play a key role in determining the well-being of Americans. Ensuring the quality of the lab tests is indeed essential to obtaining accurate results. What we are doing now regarding the assurance of the level of quality in the laboratories across the country must be reviewed with care. I commend you, Mr. Chairman for holding this hearing. I would like to note that I am particularly glad to see that there are Delawareans in the audience including Mr. Jeffrey Petrizzi and Mr. Peter Anderson who provide lab services to many people in our state.

As we all know, medical laboratories perform tests that are essential to determining whether or not someone is afflicted with a disease. When an abnormality is detected in a slide or other screening mechanism, it gives a physician an important advantage in combating the onset of a disease. Such early warning signals detected in test results can give a person a chance to a longer life. For this we are indebted to the laboratory facilities. But, rarely do we think of asking for a test to be double checked when the news is a relieving negative—meaning that every lab result must be thoroughly reviewed in the laboratory for false readings before being released. Questions as to what forms of quality controls are now in existence on test accuracy and what increases or changes in oversight of medical laboratories should indeed be investigated.

In addition, we must keep in mind that there is a delicate balance between desired guidance and overburdening the laboratories. Due to the Federal budget deficit, many reductions were made throughout government programs last December with the passage of the bi-partisan budget reconciliation bill. Specifically, laboratories across the nation did experience reductions in reimbursement under Medicare. We must proceed with caution in developing any regulations that would affect these laboratories.

Mr. Chairman, I would like to include for the Committee Record the following comments given to me by a Delaware clinical medical laboratory. These comments will help to illustrate some of the issues addressed in these hearings.

SUMMARY SHEET, MEDLAB, INC., WILMINGTON, DE

I. Medlab History

A. Over 50% of our expenses are labor. We serve more than 14,000 nursing home beds in Delaware, New Jersey, Pennsylvania and Maryland. This service involves very expensive labor costs. We must send the technician to the home to draw blood. Many times they go only for one test that is reimbursed at a very low rate, i.e., glucose $5.27. To perform a single draw glucose on a patient, (as requested by a physician) on a weekend or evening, will cost the laboratory over double what we are reimbursed. We are unable to turn down these type of medical requests because of the medical need to be performed.

Also, emergency testing at night and weekends requires us to pay our technicians 1½ to 2 times their pay rate. Once again, we lose money on all of these tests and service, yet we save the government hundreds of dollars on ambulance and hospital costs because patients do not have to be shipped to the hospital (common on weekend if no lab service is available). Round trip ambulance fare for a patient being transported to a hospital for emergency lab tests is approximately $260.000 excluding other costs, such as additional personnel and/or oxygen supplies required. This also results in a savings for the government since admitting costs and in-house testing charges in hospitals far exceed those for a technician going to a home and picking up the specimen.

B. Congress has reduced medical laboratory reimbursement by 40% and is now proposing approximately another 8.3% cut. All this has occurred since 1984. Meanwhile our pay for our technologist has increased by 15.6% since 1984, and our phlebotomists' pay, (people who draw blood) has also increased 20.1% since 1984. Even these raises have not stopped the loss of technical personnel who leave to go to industry who offer a higher pay scale.

II. Other Important Facts

A. There is a nationwide crisis regarding poor quality in laboratory tests. The press is focusing on this issue regularly on television and in print. Inadequate reimbursement results in cost cutting measures that force quality labs to close. Only unethical labs who do cut corners and do not perform quality control or meet proper standards will stay open. Even some multi-national drug company labs have been recently exposed for poor quality and inadequate testing quality.

B. There are no standards in Delaware for physician office labs or many other states. These same physicians who are not qualified to run our laboratory according to the Medicare regulations, are performing in-office testing with unqualified personnel and are being paid by Medicare. 1990 legislation is too late. Equipment manufacturers will delay or kill the regulations. Meanwhile patients die or end up with more costly treatment because of poor quality testing. All of our personnel must be qualified according to Medicare standards. Physician offices use clerical, secretarial or unqualified nursing personnel to perform the test—none have the credentials or experience needed to do such tests. This is not the level playing field we were promised in 1984.

C. Laboratories which make up a small segment of the health care providers for Medicare were the only suppliers of health care services cut so drastically in 1984. Since then no one else has been cut, only their increases were reduced. Now Medicare is going to cut us again, while only limiting the increase of physicians and hospitals! Physicians will be given a 3.6% increase for in-office, nursing home, house call and emergency room visits, and 1% elsewhere. This is a significantly higher dollar cost because they charge more per visit. Meanwhile laboratories are the only reimbursement cut that will be ½ of what it was in 1983, yet we are the most labor intense. (They also took away our promised CPI increase.) The 1984 Medicare cuts eliminated our right to bill co-insurers. Therefore 50% of the savings from those cuts went to insurance companies in most cases, (and sometimes in fewer cases the patient) but not the government.

E. We do house calls on homebound Medicare patients in Delaware. As with nursing homes, the house calls and drawing fees are inadequate, particularly for the one or two tests requests that are usually required on these visits. Our average Medicare patient payment is less than $16.00 per patient.

F. Medlab is in the laboratory business only. We cannot absorb losses as the drug companies are doing because of their other sources of profits.

G. We do not and cannot order the tests that we perform. Only a physician can do this. However, physicians that own their own laboratory can order as many tests as they want. Many cases of over-utilization are the result of this conflict of interest where the physician refers to his own laboratory or x-ray facility. Literature being used to sell in-office lab testing equipment to physicians demonstrates the profits available by over ordering and over utilizing these tests. In addition, they are not required to participate in quality control programs which add at least 30% to the test costs.

H. Many labs have gone out of business as a result of the 1984 Medicare cuts. More will go out of business if these cuts are allowed to go into effect as is.

I. The lab industry has received a disproportionately higher share of the health care cuts while being a small portion of the total health care budget. We should not be included in analysis of testing costs that include x-ray and CAT scans, etc. We are a totally different business.

J. The attached test reimbursements (schedule A) are listed from the 1983 reimbursement to the current reimbursement and then the proposed reimbursement cuts, meanwhile Medicare total expenses each year overall have increased. Where is the money going? It has certainly not been going to the laboratory industry. Everyone is going to end up paying much more to hospitals or the surviving few laboratories.

III. Conclusion, Request and Suggestions

If laboratories cannot be excluded from the next round of cuts, then the minimum amendments should be made:

1. Do not cut reimbursement for nursing home and homebound patients' Medicare laboratory tests. These have the greatest cost and include the extra services, (STATS, weekend coverage, etc.,) that cause losses for the laboratory.

2. Set up a senate committee (as has been suggested,) to investigate laboratory quality and tie this investigation into the reimbursement decreases.

3. Require all physician's laboratories performing more than 5000 total tests per year to be licensed and inspected no later than January, 1989, not 1990. Every day people suffer or die because of poor quality laboratory tests. It's a well known fact that the lower quality testing performed is in physician offices. Also, make the physicians who have a financial interest in laboratories and/or x-ray facilities, reveal

this fact to the patients so that the patients and the public will be aware of this added incentive of self-referral.

MEDICARE LAB REIMBURSEMENT CUTS

	Medicare plus co-pay 1983	Medicare[1] 1988	Cut	Percent of cut
81000—Urinalysis	6.25	3.57	2.68	43
82947—Glucose	8.00	4.83	3.17	39
80019—Chemistry profile	26.00	16.52	9.48	36
80009—Electrolytes	18.50	9.08	9.42	51
80007—SMA-6	19.00	10.43	8.57	45
82465—Cholesterol	9.00	5.98	3.02	34
85610—Prothrombin time	10.00	5.70	4.30	43

[1] By law we are no longer allowed to bill for 100% co-payor as of 1984.

Senator LEVIN. And now Dr. Wiesner. I inadvertently did not mention you in my opening statement. We are delighted to have you here.

TESTIMONY OF PAUL J. WIESNER, M.D., DIRECTOR, TRAINING AND LABORATORY PROGRAM OFFICE, CENTERS FOR DISEASE CONTROL

Dr. WIESNER. Thank you, Mr. Chairman and other members of the Subcommittee.

I am Dr. Wiesner, Director of the Training and Laboratory Program Office at the Centers for Disease Control. I will also summarize my written remarks and ask you to put those into the record.[1]

Senator LEVIN. It will be made part of the record.

Dr. WIESNER. Thank you, Mr. Chairman.

The good health of the American people is served by quality laboratory testing. Laboratory tests aid in the diagnosis and early detection of treatable disease; in the identification of risk factors; and in a proper diagnosis and medical practice.

In the past two decades there have been substantial improvements in the performance of the Nation's clinical laboratories. Regulation of these laboratories under CLIA and the Medicare-Medicaid programs, and implementation of the medical device amendments by the FDA have contributed to these improvements.

Along with technological advances, educational and training programs of professional societies, private industry and public health groups should also be credited with some of that improvement.

To put our testimony into context, however, I emphasize that the actual laboratory analysis of a specimen is just one of several important steps in the overall laboratory testing process. Laboratory testing must serve specific clinical or public health needs. Therefore, the quality of the total laboratory testing process is critical, beginning with the decision to order a particular individual test, and ending with the correct test interpretation, and communication of the results to the patient.

A modern system for further improvement in laboratory testing must address that total testing process, and recognize the changes that have occurred in laboratory testing. For example, technology has revolutionized the volume of testing and the nature of testing systems. Testing has been dispersed to an ever-widening array of clients and users, from the hospital to home kits.

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[1] See p. 279.

In response to these and other changes, the Department is considering regulatory reform. However, changes in existing regulation is neither the only nor the sufficient answer to concerns about the quality of laboratory testing.

Epidemiologic and laboratory studies into the reasons for errors in the total testing process are needed if we are going to adequately address public health concerns. The questions should not be limited to how well our laboratory analyses are being done, but rather, how well is the total laboratory testing process meeting clinical and public health needs?

With that brief overview, my remaining testimony will focus on the five areas that the committee asked us to address.

The first was the role CDC now performs in assessing the quality of Medicare and the CLIA laboratories. CDC has a dual role in assessing the quality of the Nation's clinical laboratories. First, we provide technical support to the Health Care Financing Administration, as HCFA meets its regulatory responsibilities; the details of that support are described in my written testimony. Second, the CDC conducts epidemiologic and laboratory studies to identify and resolve problems in laboratory testing.

The second area of your interest was the need for a uniform proficiency testing program. A uniform proficiency testing program would be very useful. HCFA has asked CDC to describe such a program that could be applied to Federally monitored laboratories in a uniform manner.

CDC proposed a program that contains general and specific requirements that a provider of a proficiency testing program must meet to qualify as an approved program in the areas of chemistry, hematology, immuno-hematology, and microbiology. Also included are proposed criteria for acceptable laboratory performance in each of these areas.

In December, as Mr. Hays mentioned earlier, a final version of CDC's proposal was submitted to HCFA for consideration in the Department's regulatory reform effort.

The third area to be discussed was the actions that CDC has taken in developing a PT program for cytology, focusing on pap smear test results.

The CDC has recognized for a number of years the importance of developing useful standards for cytology performance, based on sound scientific principles. On March 1st and 2nd of this year, the CDC, the National Cancer Institute of the NIH and HCFA sponsored a conference to address the quality control standards and measures for diagnostic cytology.

This conference brought together about 150 individuals representing a broad range of professional organizations as well as governmental entities. Participants discussed the important issues related to pap smear screening, and they plan to solicit comments in their subject area during individual meetings later this Spring.

We will provide alternatives to HCFA for their consideration and incorporation into a notice of proposed rulemaking.

The fourth item to be discussed was what recommendations that CDC has to improve the statutory or regulatory scheme. A very important step in improving the statutory or regulatory scheme governing Medicare-reimbursed or CLIA licensed laboratories is the leadership that HCFA has shown in proposing a regulatory package for the Department's consideration.

From a technical and scientific perspective, activities central to HCFA's balanced regulatory program are standards for internal quality control and quality assurance, and participation in proficiency testing.

There is also a strong need to undertake epidemiologic studies and demonstrations to identify and prevent costly laboratory errors, and improve the overall quality of laboratory performance.

Often the problem is not identifiable by currently acceptable procedures for internal or external quality control. The anticipated rapid changes in the Nation's laboratory system are likely to require ongoing study.

The fifth area was the progress that CDC has made in developing the so-called CLIPARS, and the anticipated utility of this data.

To put that into context, to adequately address the issue of quality of laboratory, CDC is concerned, as I mentioned earlier, about each step in the total testing process.

Selection of the appropriate test. Proper collection, labelling, transportation and storage of specimens. Application of the appropriate techniques and methods. The actual conduct of the test in the laboratory. The timely and accurate reporting of test results. Accurate interpretation of the results and application of these to patient health.

The so-called CLIPARS program was originally designed to address only two of these steps. Therefore, we have replaced CLIPARS by a series of more focused activities that I detail in the written testimony, and summarize quickly in three areas: demonstration studies to describe the magnitude of adverse health effects related to laboratory testing; analysis of proficiency testing data that are made available to us from private proficiency testing programs; and the development of a model performance evaluation program, which will focus on developing new methods, particularly in the area of HIV testing.

In summary, laboratory testing is a dynamic field. In the last 20 years, the field of medicine has seen a tremendous growth in the number of tests performed, the number of different methods available for testing, and the movement of laboratory testing into the physicians' offices.

The next 20 years will likely see comparable changes. A system to assure quality of laboratory testing must have the flexibility to adapt to changes in order to provide for the public health.

Standards of quality will change, as will the use of particular tests for particular purposes. The critical question is whether an individual laboratory result provides the information that is necessary to meet clinical and public health needs.

Recent media discussions of laboratory testing have focused on a number of very tragic cases in which death or inappropriate treatment was attributed to laboratory error.

Unfortunately, we have no measure of how frequently these incidents occur; if they are limited to certain laboratories; or if they are widespread and occur frequently in approved laboratories.

If we are to understand the causes of these incidents and develop appropriate interventions, regulatory and nonregulatory, we must conduct epidemiologic studies to determine where, how, and how frequently serious adverse effects from poor laboratory quality are served.

We believe it is possible for the Federal, State and private organizations to collaborate effectively to develop a system of laboratory testing support that is based on health requirements of clinicians, their patients and the public health.

This concludes my testimony. I will be happy to answer questions.

Senator LEVIN. Thank you very much, Dr. Wiesner. In your testimony, you indicated that the Pap smear poses a unique set of problems for controlling quality and evaluating performance. You are not yet, as I understand it, supportive of proficiency testing in the area of Pap smears, is that correct?

Dr. WIESNER. We are supportive of having proficiency testing in Pap smear testing. The issue as far as Pap smear testing is whether or not there is consensus on what is the best way to do that proficiency test.

Senator LEVIN. Are you familiar with what they do in New York?

Dr. WIESNER. Yes.

Senator LEVIN. Does their system work well?

Dr. WIESNER. New York was represented at the March 1st and 2nd meeting. And there was wide discussion among a lot of other people involved with proficiency testing for a pap smear and cytology.

The measure of whether a proficiency testing system works well is not as evident or as easy to determine as it may seem. One measure of the outcome of laboratory testing in the area of Pap smear would be the rate of severe cervical cancer cases in a given jurisdiction.

Another would be the actual accuracy rate of analysis of the pap smear in a particular program. There is not, at this present time, and we think we will be able to arrive at that, but there really isn't a consensus that the national program should be modelled after the New York State program.

Senator LEVIN. Is there a consensus that there should be a national program?

Dr. WIESNER. I think that consensus will be accomplished. I think there is wide interest in having a good proficiency testing program at the national level for cervical cytology.

Senator LEVIN. But you believe that there should be?

Dr. WIESNER. In three senses, there should be proficiency testing whenever possible for almost all analytes that are used for clinical specimens.

One is that if a program, if a laboratory is involved with a proficiency testing program, even if it isn't tied to regulation, they will get a benefit of communicating with other people who are working on similar problems, and they will get a benefit of having access to——

Senator **Levin**. Without going into the whys, do you believe there should be a proficiency testing program for Pap smears nationally?

Dr. **Wiesner**. If we can arrive at consensus on the content, the scientific content that is a useful proficiency testing program, yes.

Senator **Levin**. I'm asking you about your belief. Do you believe there should be one?

Dr. **Wiesner**. If we can arrive at that consensus, yes.

Senator **Levin**. Would you help create that consensus?

Dr. **Wiesner**. We are working very hard to do that.

Senator **Levin**. And you have made a specific proposal for one?

Dr. **Wiesner**. No, we have not made a proposal for a cytology proficiency testing program at this time to HCFA. We have called a group of people to discuss that and summarize the years of experience, both at CDC, New York State, and other places, to look at that issue.

And we believe that we will be able to come up with a consensus on the scientific application of a proficiency testing program for cytology.

Senator **Levin**. And you're saying that in the absence of a consensus, no proficiency testing program in the area of Pap smears is better than having a New York-type system?

You are satisfied as to that? You would rather have no national proficiency testing program in the absence of a consensus than have some program that has less than a consensus. Is that fair enough?

Dr. **Wiesner**. I do not think we are going to be in that option.

Senator **Levin**. You have also testified that there are other actions in addition to proficiency testing which can contribute to improved performance of Pap smear reviews. Such measures include personnel standards for cytotechnologists; limitations on the number of cytology specimens reviewed by an individual cytologist in a given time period; internal review of a certain number of smears read as negative, as well as smears read as suspicious or positive; and introduction of suspicious or positive smears into the daily workload.

Now, one by one, I would like to ask you, do you favor a national regulation or standard relative to personnel standards for cytotechnology?

Dr. **Wiesner**. There is a general consensus in the area of personnel standards of cytotechnologists and they should be incorporated into standards.

Senator **Levin**. Do you favor it, was my question?

Dr. **Wiesner**. The Centers for Disease Control has not taken an official position on that. We are still working with the professional societies, and we will be presenting these alternatives to HCFA.

Senator **Levin**. You just simply present alternatives, or do you make recommendations?

Dr. **Wiesner**. We present a proposal that has a list of alternatives, and the pros and cons.

Senator **Levin**. You don't make a recommendation to HCFA?

Dr. **Wiesner**. We do not make the decision about the content of the regulatory activity.

Senator **Levin**. Let me try again. I did not ask you if you made the decision. I asked you if you made a recommendation.

Dr. **Wiesner**. We make recommendations, right.

Senator **Levin**. Thank you. Do you have an opinion as to whether or not we should adopt personnel standards for cytotechnology? Do you personally have an opinion?

Dr. **Wiesner**. I don't think it is productive for me as a person to have an opinion, because this is a controversial area, and it is more important that we get a good scientific determination of that than for me to have a personal opinion about it.

Senator **Levin**. All right. Does that mean you do not have one, or you should not have one?

Dr. **Wiesner**. That depends on which one you are talking about.

Senator **Levin**. Try the one I just mentioned, personnel standards for cytotechnology.

Dr. **Wiesner**. I think we should—my personal opinion is that we should have one.

Senator **Levin**. All right. Now what about limitations on the number of specimens reviewed by an individual cytologist in a given time period?

Dr. **Wiesner**. I think there is close to consensus that there should be a standard for the number of specimens.

Senator **Levin**. National?

Dr. **Wiesner**. National standard.

Senator **Levin**. And about the number? Is there a general consensus as to where——

Dr. **Wiesner**. I think that is much more under question, what the number should be, should it be by year, by day, by hour.

Senator **Levin**. So you do not think there is a general consensus that it ought to be under 100 slides in a 24-hour-period?

Dr. **Wiesner**. I do not think there is a general consensus that that is the best way to state that standard.

Senator **Levin**. All right, do you have an opinion yourself on that?

Dr. **Wiesner**. I have an opinion, but it is much weaker, and I think we need a lot more advice on that.

Senator **Levin**. Okay, do you have an opinion as to whether or not there should be payment to cytologists by the piece? Should we prohibit the payment to cytologists of an amount of money based on how many specimens they look at?

Dr. **Wiesner**. CDC will not have an opinion, nor do I. The Health Care Financing Administration may.

Senator **Levin**. But you don't have a problem as to the incentive that this practice gives cytologists to do more, more, and more to make more money? That doesn't trouble you?

Dr. **Wiesner**. That is really out of our area of expertise in terms of scientific and technical areas. I would be speaking as a lay person in that.

Senator **Levin**. You do not see any medical downside to paying cytologists by the slide or by the piece?

Dr. **Wiesner**. Well, just from a general lay person's——

Senator **Levin**. Medical.

Dr. **Wiesner**. Medical point of view. Absolutely, there would be a problem if that resulted in poor quality.

Senator **Levin**. Do you think it might tend to result in poorer quality.

Dr. **Wiesner**. Absolutely.

Senator **Levin**. Thank you. We are going to follow a 10-minute rule, since we have a number of Senators here. Senator Cohen.

Senator **Cohen**. Thank you, Mr. Chairman.

Dr. Wiesner, I think in your opening statement you indicated that the quality of the total testing process is critical, beginning with the decision to order a particular laboratory test, ending with the correct test interpretation and communication of the results to the patient.

I want to ask you, is the converse also true, that a lab may have a responsibility to notify of poor testing procedures; to recall the patient as such with a notice that you may have a defective part that may be hazardous to your health?

Dr. **Wiesner**. Yes.

Senator **Cohen**. If a lab were to be put on notice by a lawsuit, for example, that a given individual did not perform a certain test appropriately, and there may have been hundreds or thousands of tests performed during a period of time, would that laboratory, in your judgment, have an obligation to communicate the possibility of incorrect testing during that period?

Dr. **Wiesner**. The legal implications of that I have no wherewithall—generally if we make a mistake, we ought to tell people we make mistakes.

Senator **Cohen**. I am just trying to clarify your positive assessment. You have an obligation, we have an obligation, to communicate correct tests. I would assume we have an obligation to communicate incorrect tests when there is a reason to believe they have been conducted.

Dr. **Wiesner**. Absolutely. I think physicians and other people running laboratories would want to do that.

Senator **Cohen**. Senator Levin asked you about proficiency testing for cytology. My understanding is that for the past 15 years you have operated an experimental program for cytology that has been given throughout the country, is that right?

Dr. **Wiesner**. Well, what we have operated is a program that some people would call a PT program. It is a matter of regional workshops where we take well defined slides. The technologists come to a central location and are tested, and them they are provided training and education based on those tests.

Senator **Cohen**. What do you call that?

Dr. **Wiesner**. That is a training workshop associated with actual slides to read.

Senator **Cohen**. And how does that differ from proficiency testing?

Dr. **Wiesner**. Well there is a whole array of proficiency testing models. One would be to mail specimens to technologists who are in a laboratory.

Another would be to actually visit a laboratory with a set of slides.

Another would be to send specimens that have already been tested by a technologist to another technologist to test.

There is a vast array of proficiency testing models that are actually under consideration.

Senator **Cohen**. You indicated in your testimony that CDC's uniform proficiency testing proposal focuses on those tests whose results are widely used, or if in error, carry a moderate to high risk of death or severe injury to the patient.

That would apply to cytology, I assume?

Dr. **Wiesner**. Sure would.

Senator **Cohen**. But it has not so far?

Dr. **Wiesner**. It hasn't—that's correct.

Senator **Cohen**. Mr. Hays, in 1981 HCFA received, under a contract to the American Society of Cytology, recommended guidelines for surveying cytology labs, and for evaluating, regulating, and improving the quality of those services in Medicare and Medicaid.

Those guidelines included workload limitations for cytotechnologists.

Yesterday we heard some rather compelling testimony that in 50 to 75 percent of the labs reviewing Pap smears, workloads were excessive up to perhaps 200 to 300 slides per day.

The question I have is, if we are losing 7,000 women a year to cervical cancer, why has HCFA waited seven years to even implement those guidelines recommended back in 1981?

Mr. **Hays**. We do plan, Senator, as part——

Senator **Cohen**. I did not ask you that. I asked you why have you waited seven years before adopting those recommended guidelines?

Mr. **Hays**. Well, I was not here in 1981, Senator, and I do not know exactly what was done with those recommendations. I do not know that they were actually received in 1981. I was under the impression that that study was commissioned in 1981.

I think it is fair to say that we have tried to improve our survey process for cytology testing, including requiring a re-review of so-called benign samples of pap smears. And we want to further improve that process, both through our new regulations, and through a contract that we are about to award in the near future, that will beef up our ability to survey laboratories in the area of cytology.

We are interested in the question of how many slides a cytotech should be reviewing. We are interested in the——

Senator **Cohen**. Why are we waiting? It seems to me that you can apply a layman's sense, without a medical doctor's testimony, saying if someone is looking at 300 slides a day, or in a 5-hour period, something is wrong.

There is nothing with respect to whether people are moonlighting, working a full job and then coming in at nighttime. There are no on-site surveys being conducted for nighttime lab work, when most of the labwork is being done at night.

You have people who may be ill-trained, over fatigued, conducting these lab analyses. And there are no guidelines coming out of HCFA. Why is that?

Mr. **Hays**. The fact of the matter, sir, is that we are addressing that problem, both through our current activities, and through the proposed regulations that we hope will be on the street by the end of next month.

Senator **Cohen**. Were these the regulations that were promised to Congress in 1986?

Mr. **Hays**. I will take your word for it, Senator. I am not aware that there was a promise of regulations in 1986.

Senator **Cohen**. So now they are going to be in April of 1988, and you hope to have cytology PT included?

Mr. **Hays**. We are certainly hoping that we will receive the material that Dr. Wiesner referred to in his testimony, so that we will be able to incorporate proposals for cytology proficiency testing in our notice of proposed rulemaking.

Beyond that, however, I don't want to leave the impression that it is only proficiency testing that we are interested in with respect to improving our regulatory oversight. We are interested in the subject of qualifications of cytotechnologists; we're interested in the issue you have raised of the number of slides; we're interested in requiring the laboratories to have a solid internal system for measuring the accuracy of the results within their own laboratory.

Senator **Cohen**. Mr. Hays, did you send a memo to Dr. Roper, the administrator of HCFA, indicating that you recommended that HCFA postpone publication of such regulations until January, 1989?

Mr. **Hays**. There may have been some questions several months ago about the scheduling of the regulation. Whether I actually sent a memo to Dr. Roper in that regard or not, I do not know. I do not recall.

Senator **Cohen**. You do not recall sending a memo that the Office of Management and Budget was concerned about the implementation date, and that you made an affirmative recommendation HCFA we delay until January of 1989 the publication of these regulations?

Mr. **Hays**. I recall the discussion of such an issue. Whether I had a memorandum to that effect, I do not recall.

Senator **Cohen**. Is that not significant?

Mr. **Hays**. The point of the matter, Senator, is that those discussions were favorably resolved in favor of attempting to expedite the publication of those regulations.

Senator **Cohen**. You mean in spite of your recommendation, they were favorably resolved to come out in April?

Mr. **Hays**. I do not recall whether I made such a recommendation, or what the basis for that recommendation was. The fact of the matter is, that substantively I have been in favor of publishing this regulation as soon as it was ready for publication.

And I am pleased to report to you that that in fact is occurring.

Senator **Cohen**. I submit for the record, Mr. Chairman, a memo indicating that Mr. Hays in fact made a recommendation, "We prefer to postpone publication until January, 1989, for the following reasons: It is a complex regulation with numerous complicated issues. For example, proficiency testing issues must be worked out with CDC, and Equipment testing issues with FDA." [1]

And other rationales, but that is, I assume, your signature. I will not take the time to have you identify it now, but that appears to be a memo from you urging delay of the publication.

Senator **Levin**. It will be made a part of the record.

Senator **Cohen**. If I could go on just for a moment, one other question for the time being, Mr. Chairman.

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[1] Available in Subcommittee files.

You indicated in your statement that generally the State validation surveys show overall agreement with the accreditation surveys. In other words, the State agencies do the validation survey for HCFA to see if the State finds the same thing for hospitals that the Joint Commission found.

Am I correct that you do validation surveys on roughly one percent of the Joint Commission hospitals?

Mr. HAYS. That is approximately the number, yes.

Senator COHEN. As a matter of fact, in 1984, the latest information we have from HCFA, the validation included 46 out of 5,200 hospitals?

Mr. HAYS. I believe that was the accurate figure for 1984. I believe that 1985 and 1986 represents a small increase over that number.

Senator COHEN. Is there any reason why we could not have had that statistical information given to us?

Mr. HAYS. Not that I am aware of. I would be happy to provide it for the record.

[The information referred to follows:]

MEDICARE VALIDATION SURVEYS FOR FISCAL YEARS 1985 AND 1986

HCFA selects, from scheduled JCAHO accreditation surveys, a statistical sample of accredited hospitals for validation surveys. State agencies (SAs) carry out the validation survey covering the two areas of Life Safety Code (LSC) requirements and general health and safety requirements which encompass all the Medicare conditions of participation. SAs also survey hospitals when there is an allegation that significant deficiencies threaten the health and safety of patients.

SAs notify all hospitals of deficiencies identified during a survey. When the SA finds a condition of participation out of compliance, the hospital must submit a plan of correction to the SA within ten days. The SA then monitors the hospital until it is brought into compliance or terminated.

FY 1985:

HCFA conducted hospital validation surveys on 4% of JCAHO's hospital surveys (66 of 1,536).

Evaluation showed comparable survey findings: nonserious deficiencies were identified by 89% of the JCAHO surveys and 80% of the validation surveys.

63% (42 of 66) of the validated hospitals were in compliance with LSC requirements. It should be noted that those hospitals found out of compliance were often for serious deficiencies that could, however, be easily corrected (e.g., by closing fire doors that inspectors had found propped open) bringing the hospital quickly into compliance.

80% (53 of 66) of JCAHO accredited hospitals were found by the validation survey to be in compliance with Medicare's general health and safety conditions.

SAs surveyed 398 accredited hospitals based on allegations of significant deficiencies that could affect the health and safety of patients.

11% (42 of 398) were out of compliance with one or more conditions.

1% (5 of 398) were out of compliance with the LSC.

4% (17 of 398) were out of compliance with the nursing condition.

2-4% were out of compliance with other general health and safety requirements.

Considering both validation surveys and complaint investigations, SAs found that 80% of all hospitals surveyed were found in compliance with all conditions of participation.

FY 1986:

HCFA conducted hospital validation surveys of 5% of JCAHO's hospital surveys (48 of 992).

Evaluation showed comparable survey findings: nonserious deficiencies were identified by 94% of the JCAHO surveys and by 90% of the validation surveys.

93% (46 of 48) of validated hospitals were in compliance with the LSC.

83% (40 of 48) of JCAHO accredited hospitals were found by the validation survey to be in compliance with Medicare's general health and safety requirements.

SAs surveyed 402 accredited hospitals because of complaints of significant deficiencies that could jeopardize patient health and safety.

11% (45 of 402) were out of compliance with one or more conditions.
4% (15 of 402) were out of compliance with the nursing condition.
0–4% were out of compliance with other general health and safety conditions.

Considering both validation surveys and complaint investigations, SAs found that 88% of all hospitals surveyed were in compliance with all conditions.

Senator COHEN. It is my understanding that about half of those validation surveys involve hospitals with labs accredited by CAP, is that correct?

Mr. HAYS. I do not know precisely. Certainly, given the fact that the Joint Commission uses CAP for a number of its laboratories, I would assume that a representative sample would be included.

Senator COHEN. But the problem is that HCFA doesn't validate CAP accreditations, do they?

Mr. HAYS. Per se, we validate the JCAH accreditation. JCAH in turn, in certain cases under law, has the ability to delegate the accreditation of labs to CAP.

Senator COHEN. Why do you not validate CAP?

Mr. HAYS. I would suggest that we do by virtue of our validation surveys in hospitals that include laboratories that have been accredited by CAP.

Senator COHEN. Well, as I look at the statistics out of that one percent, half involve CAP inspection results that are not validated by HCFA, which means you are looking at about half of one percent of all of the hospitals to evaluate performance of the Joint Commission.

Mr. HAYS. I guess I am perhaps confused, or perhaps we have a semantics problem.

The fact is, we survey laboratories as part of our validation survey of hospitals, whether that laboratory was under CAP accreditation or not. And if there is a problem in that laboratory identified in our validation survey, we take action, regardless of whether it is CAP accredited or not.

So we do review in those surveys the validity or the compliance of hospital laboratories whether they are CAP accredited or not.

Senator COHEN. I am under the impression from talking with members of your staff that HCFA does not, in fact, validate those performed by CAP. But that is a matter we can debate later.

I was going to ask you the following question. Assuming that that one percent includes the CAP——

Mr. HAYS. I think, Senator, the confusion is whether or not we receive from the JCAHO the information from CAP, prior to surveying the laboratory.

And I understand that, heretofore we have not. And we are now talking to the Joint Commission about receiving the information from CAP before we do a validation survey of a hospital which has a CAP-accredited laboratory.

Senator COHEN. In any event, as of 1986, in validating the Joint Commission, HCFA found it necessary, I think, to place 8 percent of hospitals under the State agency monitoring because the condition of laboratory services was found to be out of compliance.

The question I have is, if you have such a small sample of either one percent or half of one percent, but call it one percent, and you find eight percent deficiencies, so that the hospitals have not met the standard compliance levels, does that not tell you that you may be sampling too small a proportion of the hospitals?

Mr. **Hays**. I certainly would not argue that we could have some benefit from additional validation surveys.

Senator **Cohen**. Well, if one percent gives you eight percent deficiencies, wouldn't you think that you would want a bigger sample?

Mr. **Hays**. Well it is not clear that doing a five percent sample would result in identifying a higher percentage of deficiencies.

I certainly am not going to argue against the notion of doing more surveys.

Senator **Cohen**. Are you going to recommend that? It is not a question of whether you argue with me or not. Are you going to recommend it?

Mr. **Hays**. I think we will recommend some increase in survey activity across the board, including, but not limited to, validation surveys.

Senator **Cohen**. Mr. Chairman, I will come back.

Senator **Levin**. Thank you. Senator Heinz?

Senator **Heinz**. Mr. Chairman, thank you.

Let me ask either of you, how important is it that we know roughly how many tests are being done each year, and what kinds of tests they are? Is that important or unimportant? Mr. Hays?

Mr. **Hays**. Well, I guess I think it is less important in general to know what kind of ~~tests, or~~ rather, how many tests are being performed, as opposed to the outcomes, the quality and accuracy of those tests.

Senator **Heinz**. Is it relevant to know how many highly critical tests are being performed each year?

Mr. **Hays**. Again, I think it is probably more relevant to have, for example, a good proficiency testing program for those highly critical tests than it is to know exactly how many are being performed.

Senator **Heinz**. Dr. Wiesner, do you want to answer those two questions?

Dr. **Wiesner**. I think it is important to know the number of tests if you are going to plan proficiency testing, and identify areas where it is important to do it in.

Senator **Heinz**. A moment ago, in response to a question from Senator Cohen, Mr. Hays indicated that he would not argue against increasing the sample from one percent.

The whole idea of statistics is to have a sample that is related to the size of the population that you are sampling. Dr. Wiesner, you know that. You are trained in these things. Is that not correct?

Dr. **Wiesner**. That is a general principle of epidemiology.

Senator **Heinz**. Yes. How many tests have been performed in any one year period? How many sickle cell tests have been performed?

Dr. **Wiesner**. I don't know the answer to that question.

Senator **Heinz**. How many hepatitis tests have been performed?

Dr. **Wiesner**. We can get these answers for the record. But I do not know the specific answers to each one of these tests.

Senator **Heinz**. I think you are going to have grave difficulty getting the answers, because nobody has them.

What that means is that any statistical validation of error rates is, other than overall, absolutely meaningless, unless someone can produce the specific numbers for individual tests.

The 8 percent may have validity across all tests, but it could be 50 percent for a small number of absolutely critical tests. It might be one percent for throat cultures, or relatively routine urinalyses that are of relatively modest criticality. I'm not an expert. I don't know which are or which aren't critical.

I do not hear anybody rebutting that, so let me go on. I think it proves, if I may say so, Mr. Chairman, that we are in the dark ages in terms of knowing what is going on, let alone measuring the incidence of error.

I might add, just for the record, that to the extent we have any statistics, they do not come from the Federal Government. They come from—guess where—the College of American Pathologists, CAP, a deemed institution.

Several witnesses yesterday criticized the approach we took to regulating physician office labs under OBRA in 1987, where only physician office laboratories with 5,000 or more annual tests as of 1990 are going to be regulated.

Do you see merit in their position that regulation should be tied to the complexity of the test involved instead of test volume, Mr. Hays?

Mr. HAYS. I certainly think that is an issue that needs to be carefully examined.

Senator HEINZ. You are not going to examine it in your regulation?

Mr. HAYS. As you know, Senator, the OBRA 1987 provision goes into effect on January 1 of 1990. We are about to submit a report to Congress which will indicate that it is extremely difficult to determine how to go about this, and whether the 5,000 approach is the best way to go.

Senator HEINZ. You have no feel for that one way or the other?

Mr. HAYS. Without flatly stating that there is a better way of doing it, I would say that I share the concern, whether the 5,000 approach is the way to go.

Senator HEINZ. Do you think the Pennsylvania way is a better way?

Mr. HAYS. Well, I understand that was discussed yesterday. I must say, I am not personally familiar with the Pennsylvania approach.

Senator HEINZ. Would you like to take a look at that and then give us your response?

Mr. HAYS. Surely.

[The information referred to follows:]

We are presently examining different approaches to Federal regulation of physician office laboratories (POLs). Pennsylvania's regulatory system classifies labs into 3 levels corresponding to the range of testing done by the POL. Upon initial review, Pennsylvania's system appears administratively difficult. The 3-level classification system warrants constant reevaluation and revision because innovative technologies are constantly changing the skills needed to perform many of the tests.

Pennsylvania's regulatory system also fails to incorporate outcome measures of quality in the requirements for level 1 laboratories (those performing the smallest or least complex range of services). We believe that even if the test complexity is minimal, external measures of performance are essential to any regulatory program.

Senator HEINZ. I am not asking you to commit yourself to the Pennsylvania way. Just tell me if you think it is a better way than the way we have under OBRA 1987.

Mr. HAYS. I certainly would be pleased to do that.

Senator HEINZ. What steps at this point has HCFA taken to implement its new authority to impose a rather broad range of intermediate sanctions and penalties on clinical labs that are out of compliance with Medicare conditions for participation? What have you done to use any of that authority?

Mr. HAYS. That also, Senator, has an effective date of January 1st, of 1990. We are required to go through a public rulemaking process to implement that provision, which we will be beginning shortly.

And we fully expect to be able to use it by the time it is effective.

Senator HEINZ. Do you see any barriers to taking full advantage of that authority?

Mr. HAYS. I do not think so. I think, however, that ultimately the most effective tool in our arsenal, if you will, is the ability to outright terminate a laboratory from participation in the program.

Senator HEINZ. What steps is HCFA taking to limit the opportunity for joint ventures and induced referrals between physicians and clinical labs that you refer to you in your testimony?

It seems to me that a system that encourages or fails to crack down on physicians who order tests for purposes of profit rather than for care is not only costly but impacts quality by subjecting beneficiaries to more tests and a higher risk of error.

Mr. HAYS. Well, we are certainly concerned about that from the issue of overutilization and exposing patients to unnecessary risks.

In terms of our ability to regulate it from a payment perspective, there is not a lot that HCFA can do directly, because of the way in which payment for laboratory testing works under Medicare.

We are working, of course, with the Office of the Inspector General. They have a number of investigations underway to look at kickback and fraudulent situations.

We are also increasingly interested about the connection between the possibility of fraudulent payment practices on the part of laboratories, and poor quality problems.

So we want to establish a better link between the Inspector General's type of activity that ferrets out fraudulent payment problems, and our quality review system.

Senator HEINZ. Do you have all the utilization information that the office of the OIG would need?

For example, it would seem to me that since there are arrangements in effect where physician-owned labs and others would reward high volume referrers with discounts on lab bills, you have an incentive to overutilization.

Do you have information both on the high volume labs, and on the specific incentives? Do you keep track of the costs and prices?

Mr. HAYS. Well, from the physician side, to the extent that the physician is ordering too many tests, we do have the ability through our Medicare carriers to review and oversee that.

From the standpoint of the way in which we have to pay laboratories, our authority, as you most likely know, is limited by law. And we are interested in new ways of paying for laboratory services which we think would be more economical to the Medicare program and less subject to abuse.

Senator HEINZ. One last question, Mr. Chairman. How is HCFA building quality oversight of physician office labs into other physician utilization and quality review initiatives?

Does it make sense, for example, to include a POL review in the pilot test being planned for PRO review of physician offices? Those pilot tests are supposed to begin in January.

Mr. HAYS. Well, I do think that there is certainly the potential for linkage between the upcoming peer review organization review of physician offices, and the requirement for regulating physician office laboratory activities.

And that is a subject that I have asked our staff, who are responsible both for the PRO program and for the laboratory regulation to begin to examine.

Senator HEINZ. Let us turn the question around. You are going to look at physician offices. Is there any case to be made not to look at the lab?

Mr. HAYS. I guess the only question is whether the peer review organizations are currently equipped adequately to examine laboratory testing directly.

Senator HEINZ. I am not talking about implementation. I am talking about building it into your pilot tests. Is there any reason not to do that?

Mr. HAYS. Not that has come to my attention. And it is an area that I am interested in, and we will be looking at it.

Senator HEINZ. I commend you on your interest. I will assume, if I may, one of two things. Either that you will do that, or if you don't, you will let us know ahead of time that you are not going to?

Mr. HAYS. Certainly, I would be happy to do that.

Senator HEINZ. Thank you. You have been most responsive. I appreciate your very direct answers to my questions.

Mr. HAYS. Thank you.

Senator LEVIN. Thank you, Senator Heinz.

Mr. Hays, who enforces HCFA's regulations governing medical laboratories?

Mr. HAYS. That responsibility depends on definition. We have agreements with all of the States under Federal law, and they, through their State survey organizations, do the bulk of the on-site inspection.

We have our own Federal survey staff who conduct what we refer to as Federal monitoring surveys to make sure that the State agencies are properly carrying out their responsibilities.

In the final analysis, we, the Health Care Financing Administration, have the responsibility for enforcing those requirements.

Senator LEVIN. All right. And is that also true with CAP?

Mr. HAYS. I am not sure I quite understand the question.

Senator LEVIN. Well, you talked about State agencies. Now I want to ask you about CAP. As I understand it, CAP does some regulation in the area of interstate labs. And those are the labs I want to focus on in this question, not the hospital labs, just the interstate ones.

Mr. HAYS. If you are referring to those laboratories which are exempt from CLIA because they are CAP-accredited, we do not, as I understand it, have any direct authority over CAP.

That is a statutory designation of their ability to accredit those laboratories, which exempts them from direct CLIA regulation.

Senator LEVIN. Do you do any review of their accreditation at all?

Mr. HAYS. Only in the indirect sense that we were discussing earlier, to the extent that they have accredited hospital laboratories——

Senator LEVIN. No, I am not talking about hospital labs.

Mr. HAYS. It would only be in the indirect sense that if we survey a independent laboratory, which is participating in Medicare or CLIA, which happens to also have CAP accreditation, it could be said, I suppose, that we are looking at their accreditation program.

Also, as you probably know——

Senator LEVIN. I am just talking about interstate labs which are not under the Medicare coverage or program.

Mr. HAYS. If they are exempt from CLIA because of CAP, the answer is no. As you probably know——

Senator LEVIN. All right, let us just focus on that. There is what, maybe 300 or 400 labs such as that?

Mr. HAYS. I believe there are 400-some CLIA exempt labs because they have CAP accreditation.

Senator LEVIN. Okay, and you are saying that you have no right under the law to oversee CAP in their accrediting process; is that correct?

Mr. HAYS. That is my understanding.

Senator LEVIN. Did the Centers for Disease Control ever do any oversight work relative to CAP accreditation in those labs?

Dr. WIESNER. No.

Senator LEVIN. So that was never done by CDC?

Dr. WIESNER. Previously, you mean when we had responsibility for it before 1976 or 1979? I cannot answer that question. I would have to ask somebody.

Senator LEVIN. All right. Now, what kind of statistical information, Mr. Hays, do you get from the Joint Commission and CAP on their laboratory review?

Mr. HAYS. We get information from the Joint Commission in relation to our validation surveys of JCAHO accredited hospitals.

Senator LEVIN. That is the one percent. Now, beyond that, what kind of statistical information do you get from the Joint Commission and CAP on their lab reviews?

Mr. HAYS. I do not know whether we receive further information. I would be happy to provide that for the record if we do.

[The information referred to follows:]

HCFA receives statistical information from the Joint Commission on the hospital laboratories involved in validation surveys and complaint investigations. To date, we have not received information from CAP-accredited hospital or CLIA-exempt independent labs.

We will be working with the JCAH and CAP to obtain annual summary data on inspection findings.

Senator LEVIN. Well, at a minimum, shouldn't you be getting statistical information from the Joint Commission and from CAP on their surveys? You surely have the right to do that, don't you, under the law?

Mr. HAYS. We probably have the right to request it. I do not know that we have the right to insist on it.

Senator LEVIN. I thought you said you were the ultimate authority here?

Mr. HAYS. But under the law, the Joint Commission has deemed status, which for Joint Commission accredited hospitals substitutes for our authority, with the exception of those hospitals which we end up surveying either because of a validation survey or because of a complaint that leads to an investigation.

Senator LEVIN. But I asked you before, who enforces HCFA's regulations governing medical labs, and your answer was, you are the ultimate enforcer of your regulation. Is that correct or not?

Mr. HAYS. Well, that is a correct statement within the context, however, of deemed status for the Joint Commission.

Senator LEVIN. Okay, on those labs which have deemed status, are you saying you are not the ultimate enforcer?

Mr. HAYS. Our role is certainly different with respect to those.

Senator LEVIN. Are you the ultimate enforcer relative to those labs or not?

Mr. HAYS. I would say only to the extent that we do a validation survey or a survey as a result of a complaint.

Senator LEVIN. Which is one percent?

Mr. HAYS. Well, we do a higher number of complaint investigations?

Senator LEVIN. Two percent? Three percent?

Mr. HAYS. Something in that neighborhood.

Senator LEVIN. Okay, so that in 97 percent of the labs, you are saying, where the accreditation is done either by CAP or by the Joint Commission, you are not the ultimate enforcer of Federal regulations.

Is that a fair statement?

Mr. HAYS. Well, I think it is a fair statement, Mr. Chairman, to say that the Congress itself has established the Joint Commission position.

Senator LEVIN. I understand that. For whatever reason, whether it is by law or by your own decision, you are not the ultimate enforcement body on those 97 percent of the labs that I just described. Is that correct?

Mr. HAYS. Unless we receive a complaint about one of those labs.

Senator LEVIN. I covered those. That is why I said three percent instead of one percent.

Mr. HAYS. But that refers to the ones we have done. We might get a complaint tomorrow about one of the 97 percent, in which case we will go in.

Senator LEVIN. What percentage of the labs do you get complaints against a year?

Mr. HAYS. It is a very, very small number, on laboratories.

Senator LEVIN. Pick a number, one percent, two percent?

Mr. **Hays**. I think smaller. I think we have received something like 30 complaints over the last several years on laboratories only.

However, we also receive a larger number of complaints about hospitals in general.

Senator **Levin**. Then except for that small percentage of labs over which you do your validation survey, and except for those very few labs you get a complaint against, you do not view yourself as the ultimate enforcer of Federal regulation for whatever reason; is that fair?

Mr. **Hays**. Yes, at the risk of repetition, with the exception of the extent to which we do ultimately go into one of those hospital laboratories.

Senator **Levin**. Didn't I just say that? Didn't I just say with the exception of those that you've received complaints against and go in and review, and with the exception of the roughly one percent that you do validation surveys of, you do not view yourself as the ultimate enforcer of Federal regulation for those labs? Is that a fair statement?

Mr. **Hays**. Again, Mr. Chairman, yes, except that if we, beyond those that we have already looked at, get a complaint today or tomorrow or next week, we will go in and we will exercise the authority.

But the role is fundamentally different.

Senator **Levin**. Except for that small number of labs, who is the ultimate enforcer? Except for your little qualifier, which is the same as my qualifier, except for that qualifier, that leaves 97 percent of the labs over here.

Who is the ultimate enforcer of the Federal regulation for those labs, would you tell me? Just who?

Mr. **Hays**. I think it is a shared role.

Senator **Levin**. You do not enforce it to those——

Mr. **Hays**. We do not annually survey those laboratories the way we annually survey the independent laboratories; that is correct.

Senator **Levin**. And do you think that the College of American Pathologists consider themselves to be the enforcer of Federal regulations?

Mr. **Hays**. No. Their position is a contractual relationship, as I understand it, with the Joint Commission.

Senator **Levin**. My question is, do you think that the College of American Pathologists views itself as the enforcer of Federal regulations? That's my question.

Mr. **Hays**. I think you would have to ask CAP.

Senator **Levin**. Don't you know?

Mr. **Hays**. I would guess that they do not view themselves in that role.

Senator **Levin**. Well, you ought to know. That much you ought to know, it seems to me. I am being real blunt here. You ought to know whether or not the College of American Pathologists views itself as the enforcer of Federal regulations.

It is your guess that they don't. Let me read you their testimony:

> It is important to recognize that the CAP program is designed to foster laboratory improvement and assist any laboratory wishing to meet the standards required for accreditation.

This is in direct contrast to State and Federal programs designed to determine strict compliance with regulatory requirements and initiate punitive actions for noncompliance.

They do not consider themselves as the enforcement agent. And you are not the enforcement agent in 97 percent of the cases. Ergo, math leaves us with the following conclusion: Nobody is enforcing Federal regulation in 97 percent of these labs, except to the minor extent that you might get a complaint against a lab. That possibility is the one that you hold out in the future, and you have had about 30 such complaints in the past few years.

Except for that, there is not a crack that this enforcement responsibility has fallen into. There is a crevice.

Now it may be that Congress has not made it clear enough who the enforcer is; in which case, we ought to correct that. It may be that you have not, that HCFA has not, done the enforcement which the law anticipated that HCFA would, which at a minimum would, I think, be oversight. At a minimum, you ought to get information on, and you ought to get statistical data from, CAP.

I mean, I think at an absolute minimum we expect the Joint Commission and CAP to furnish you, and we expect you ask them for, statistical data. That seems to me minimal. But you are not sure whether you get that data.

Mr. HAYS. We will certainly pledge to you that we will review that issue of the information. Beyond that——

Senator LEVIN. Well, in terms of oversight, that is pretty minimal. That is really minimal, it seems to me. We have the major question, who is going to enforce Federal regulations? And at the moment, as far as 97 percent of these labs are concerned, nobody is.

Because the people who are accrediting them do not view themselves as enforcement agencies. You do not do the enforcement except for that narrow exception you mentioned, which amounts to about 3 percent of the labs; one percent being the ones that you do that validation survey on, and the other ones being the ones you get complaints on.

So there is the crevice.

Mr. HAYS. But again, Mr. Chairman, under the law, the Joint Commission enjoys deemed status.

Senator LEVIN. Under the law, you have a right, do you not, to obtain statistical information from those two entities? Is that not correct?

Mr. HAYS. I think I indicated earlier, sir, that I am not certain at this point that we have the right to obtain it, as opposed to the right to request it.

And that is what I will be more than happy to look into.

Senator LEVIN. Whether you have the right to obtain or the right to request, you have not done either?

Mr. HAYS. Well, we certainly have with respect to validation surveys.

Senator LEVIN. No, come on. I am talking about the 97 percent. Not the validation surveys. That is one percent. As to the 97 percent I have tried to identify, you have not done either; is that not fair?

Mr. HAYS. I am not sure, sir.

Senator LEVIN. I have an exclamation point that my time has expired. Senator Cohen?

Senator COHEN. Mr. Hays, yesterday Dr. Hoffman and Dr. Dickerman of New York State expressed some concern in their written testimony that Pap smears were being screened in physicians' offices.

Are physicians being reimbursed under Medicare for Pap smears conducted in their office?

Mr. HAYS. To the best of my knowledge, yes.

Senator COHEN. Are you concerned, are HCFA concerned, that Pap smears, which are very highly subjective, and depend on the judgment of the person reviewing them, are being read in an unregulated environment, namely, the POLs?

Mr. HAYS. We certainly are concerned about quality in physician office labs in general, and cytology, as in nonphysician office labs, would be a particular area of concern.

Senator COHEN. Do you plan to include POLs in your regulations that are coming out in April?

Mr. HAYS. We do not currently plan to do that. We do plan to comply with the January 1, 1990 effective date of the requirement to regulate physician office labs performing 5,000 or more tests annually that Senator Heinz and I were discussing earlier.

Senator COHEN. But if they are in fact performing these types of tests, which are crucial, why wouldn't HCFA want to have the same standards imposed on physicians who conduct these tests as they would on labs?

Mr. HAYS. Well, that certainly is a fair question. I should add by the way that I am not totally clear on the extent to which Medicare pays for routine Pap screening tests when performed in the physician's office.

Senator COHEN. Doesn't HCFA have access to that kind of information?

Mr. HAYS. I am sorry?

Senator COHEN. Do you not have access to that kind of information? You would inquire, for example——

Mr. HAYS. Whether we pay for it?

Senator COHEN. Whether it is being reimbursed under Medicare?

Mr. HAYS. Yes, certainly. Yes. I am just not the personal expert in that area.

Senator COHEN. I understand. But you could get that information?

Mr. HAYS. I believe so.

[The information referred to follows:]

Data from 1986 show that about 42 percent of Medicare Pap tests were billed from physician offices. Because these data do not separate the setting where the smear was taken from the setting where the smear was read, we do not know what number of these slides were read in physician office labs or sent to other laboratories to be read.

Senator COHEN. Let me turn to AIDS and drug testing. Can I ask you why the proposed National Institute for Drug Abuse regulations for drug testing are different from the current lab testing regulations?

Mr. HAYS. Different than the existing lab regulations, or the proposed lab regulations?

Senator COHEN. Both.

Mr. HAYS. The drug testing regulations, first of all, emanate from another part of the Department. Those guidelines do not fall within my jurisdiction.

They are certainly different from the existing Medicare regulations, because it is a new field which represents change in technology since the existing regulations were published.

Senator COHEN. Is drug testing more important than testing for cervical cancer?

Mr. HAYS. Certainly not.

Senator COHEN. For glucose testing?

Mr. HAYS. My understanding from the people who are responsible for the so-called NIDA drug testing guidelines is that they felt that there was some difference needed because of the rather limited nature of their activity as opposed to the literally thousands of tests that we perform under Medicare and CLIA, and the fact that drug testing is in the forensic arena, so to speak, as opposed to the medical-clinical arena. But I guess for a fuller discussion of that, we would need to have representatives of that part of the Department here.

Senator COHEN. Wouldn't you think tests in the medical arena would be more important than those in the forensic arena, or just as important?

Mr. HAYS. Certainly for those that have life-threatening implications.

Senator COHEN. Well, these particular regulations call for blind proficiency testing; more frequent proficiency testing; higher passing scores for proficiency testing; more quality control runs; more frequent inspections by larger and more experienced teams.

The question I have is, why should we have one arm of the Federal Government in a particular field having a different set of regulations for something that might be equally if not greater in its importance and its consequence?

Mr. HAYS. Certainly, I do not question the issue of importance. I think the major difference——

Senator COHEN. Let me just ask you: Why do you not use their standards, as opposed to having them perhaps being asked to use yours?

Mr. HAYS. That is what I am getting at, I guess. The major difference, I believe, is the fact that the NIDA guidelines apply to, I believe, five tests conducted by what would probably be a handful of laboratories for a very small subset of the population.

And I think it is simply not feasible, maybe desirable, but simply not feasible to apply identical approaches, particularly in Medicare, where we are talking about thousands of different tests; a volume of millions of tests performed in thousands of laboratories. To have precisely identical approaches to proficiency testing, for example, blind proficiency testing, is simply not technically possible.

Senator COHEN. Mr. Hays, under CLIA which has been with us now for some 20 years, some States have not regulated labs, they do not regulate labs that do intrastate type of testing, and do not receive Medicare reimbursement.

Do you intend to cover those labs that are not currently covered under the CLIA law in your regulations? In other words, would you extend it to those who do not receive Medicare reimbursement, who conduct their tests solely within a State?

Mr. HAYS. To the best of our knowledge, our proposed regulations would not address those. And I believe that the position would be that we would currently lack the legal authority to cover those.

Senator COHEN. Do you think that we ought to amend the law to cover those?

As a practical matter, if you have faulty lab testing being done within a State, a person isn't apprised of a condition that he or she might have, and they end up going to the hospital for a surgical treatment, all of which may be reimbursed by Medicare or Medicaid. Ultimately the taxpayer is picking up the bill, and yet there is no oversight of those particular labs.

Mr. HAYS. From a policy perspective, it is difficult to see why those laboratories should be subjected to oversight.

Senator COHEN. I mentioned in my opening statement that we seem to have a rather inconsistent situation, where the Medicare reimbursement system, and the manner in which Medicare certifies laboratories, creates a situation in which a lab that is stopped from performing a test under the CLIA law can still receive Medicare reimbursement for that test.

Why should the Federal Government continue to pay for tests under Medicare with one hand while you might object to the quality or the qualification of that lab to perform the test in the first instance? Why should we do that?

Mr. HAYS. Well, I hope to the extent permitted by law, that that will not occur.

Senator COHEN. It does occur now.

Mr. HAYS. It should not occur with the change in the regulations, and with the uniform national proficiency testing program which will be applicable across the board, both to CLIA and the Medicare.

Senator COHEN. Now, as I understand it, CDC has taken itself out of the proficiency testing business; is that right, Dr. Wiesner?

Dr. WIESNER. We have stopped producing the samples, packaging them up and sending them out. We have not taken ourselves out of the proficiency testing.

Senator COHEN. Is there a grading system currently in existence for proficiency testing?

Dr. WIESNER. There is a grading system for proficiency testing for the CLIA laboratories. But there isn't a grading system that can be applied to those laboratories at this time.

Senator COHEN. What are you saying?

Dr. WIESNER. When we stopped——

Senator COHEN. We have a grading system, but we cannot apply it, therefore we cannot enforce it against laboratories We have no standard to measure laboratories against?

Dr. WIESNER. At this time that is the case for the laboratories that are being surveyed for CLIA; that is correct.

Senator COHEN. Is that something that is going to be addressed?

Dr. WIESNER. That is the major effort as far as the uniform proficiency testing program, is actually for the first time to get a uniform scoring system, not just applied to the interstate laboratories, but all of the Federally monitored laboratories.

That is what the proposal is. And that is moving a scoring system and a proficiency testing system from covering only a small number of laboratories to all Federally monitored laboratories.

Senator COHEN. Mr. Hays, Senator Levin asked you about HCFA's delegation of responsibility to the Joint Commission. Under HCFA's regulations, I believe you require unannounced inspections, and in fact have advocated this in meetings with the Joint Commission; is that not correct?

Mr. HAYS. We certainly prefer unannounced surveys for labs.

Senator COHEN. Prefer or require?

Mr. HAYS. Well, we require unannounced surveys in our own surveys of independent labs, and are interested in extending that to hospital laboratories as well.

Senator COHEN. Now the Joint Commission announces their inspection anywhere from four to six weeks in advance. The question I have for you is how can an announced inspection allow you to see a true picture of the daily activity in a hospital lab?

Mr. HAYS. Well, certainly that is why we would prefer to have unannounced inspections.

Senator COHEN. Not prefer; require. You require unannounced inspections. That is not being done. What are you doing about it?

Mr. HAYS. As you suggested, we have discussed this matter with the Joint Commission. But I do not believe we have the authority to require the Joint Commission to change its procedures.

Senator COHEN. In other words, Congress passes a law giving you the principal enforcement responsibility, and delegates that responsibility in the form of deemed status to the Joint Commission and to CAP. You have certain regulations requiring unannounced inspections.

The Joint Commission does inspections on four to six weeks notice, and you have no authority to insist that that be terminated?

Mr. HAYS. My understanding is that under the statutory deemed status that the Joint Commission specifically enjoys, we do not have that authority.

Senator COHEN. Dr. Wiesner, I don't want you to feel neglected. We heard some criticism yesterday that CDC's proposed grading system is too lenient and would allow labs with marginal performance to continue under Medicare and CLIA.

If, for example—my time has expired, but I will finish this one question—if a lab got seven out of ten chemistry PT tests right, it would score seventy percent in chemistry, which would be considered acceptable performance under CDC's proposal; is that correct?

Dr. WIESNER. That is correct. This is a sequence of three surveys; you have to maintain a cumulative average of seventy percent.

I think we have to view the scoring system like we are viewing laboratory tests. Laboratory tests have some intrinsic false negatives and false positives, and therefore on occasion, very unfortunately, people who don't have the disease get labelled as having the disease and vice versa. Similarly, a scoring system on a proficiency testing program, when it is applied to laboratories, can make an error; the proficiency testing system in any kind of scoring scheme can make an error and say that a laboratory that actually is providing good service and should be maintained as good service is in error, saying that erroneously, and also go to a laboratory that is performing poorly and potentially saying that that laboratory is okay.

Any scoring system that we examine and put forward will have a balance between falsely identifying laboratories as having a problem and stating that some laboratories who don't have a problem actually do.

Now, that balance has to be struck by identifying ways to really focus efforts to address laboratories that are performing poorly.

The scoring system that we proposed was a merger of the previous CLIA and the best of the Medicare regulations. It takes under consideration that any proficiency testing scoring system really cannot tell you whether a particular value has clinical relevance, and it also takes into consideration that you need to measure the performance of that laboratory over time.

Those considerations are not easy to make. There is a balance between overcalling and undercalling, and the focus of the scoring system is an attempt to present that balance.

Senator COHEN. Can you tell me why the National Institute for Drug Abuse would insist on such an unreasonably high expectation of a ninety percent proficiency test score?

Dr. WIESNER. I cannot answer that question.

Senator COHEN. We have more questions, Mr. Chairman, and I would like permission to submit questions to both of our witnesses for the record.

Senator LEVIN. We will keep the record open.

We appreciate our witnesses being with us. I have just a couple of additional questions before we release you.

Mr. Hays, back to our conversation before, let me just summarize it. We have no Federal enforcement mechanism for Federal regulations in Joint Commission and CAP laboratories by Congressional design.

Is that a fair statement?

Mr. HAYS. I am afraid that is essentially the net effect.

Senator LEVIN. Okay. We have created a gray area in our statute; is that not basically the bottom line, in terms of ultimate enforcement?

Mr. HAYS. It is at least gray, yes.

Senator LEVIN. At least gray at a minimum. That is Congressional statute which did that.

Mr. HAYS. Yes.

Senator LEVIN. Rightly or wrongly, and that is obviously one of the things we have to look at.

Mr. HAYS. Yes

Senator LEVIN. But the area where you may have authority—and you do not know if you do or not, and you don't know if you have sought to exercise it—is in seeking information from those laboratories so we could get a handle as to, for instance, how many labs have been cited for deficiencies or how many have been decertified—is that fair?

Mr. HAYS. Yes.

Senator LEVIN. Okay. So what we can do immediately is try to start that process; at a minimum, we can ask for that information.

Mr. HAYS. Yes.

Senator LEVIN. All right. That will then, it seems to me, allow Congress to make a better decision as to who is going to enforce Federal regulations, because right now there is no ultimate enforcer in these labs.

Mr. HAYS. We would be happy to cooperate in that endeavor.

Senator LEVIN. Real good. Now, my last question. Back to the Pap smear test issue—right now, we require no certification testing, as I understand it, for persons who read Pap smears. Is that fair? There is no certification testing.

Mr. HAYS. I believe that is correct.

Senator LEVIN. And should we not at a minimum require certification testing for people who read Pap smears? Most of our States even require licensing for people who cut hair.

Mr. HAYS. We are strongly considering including in the Notice of Proposed Rulemaking a requirement for qualifications for cytotechnologists.

Senator LEVIN. Would that include certification testing?

Mr. HAYS. Honestly, I am not sure.

[The information referred to follows:]

The Notice of Proposed Rulemaking is in the clearance process and will address personnel issues.

Senator LEVIN. Let us know if it does, and if not, why not, because it would seem to me we ought to have that at a minimum.

Mr. HAYS. Thank you very much.

Senator LEVIN. To both of you gentlemen, thanks so much.

If we could come to order, our next panel is made up of Dr. Dennis S. O'Leary, President of the Joint Commission on Accreditation of Health Care Organizations and Dr. Loyd Wagner, who is the Vice President of the College of American Pathologists.

We are grateful for your being here and for your patience. We probably told you you would be on no later than ten o'clock, and here it is after eleven o'clock, but we are grateful that you are here. We would also appreciate it, as you proceed, if you would summarize your statements so we would have time for questions and if you would introduce the people you have with you.

Dr. O'Leary, why don't we start with you?

TESTIMONY OF DENNIS S. O'LEARY, M.D., PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS,[1] ACCOMPANIED BY CLIFFORD HOUSER, ASSOCIATE DIRECTOR FOR MEDICAL TECHNOLOGY

Dr. O'LEARY. Mr. Chairman, I am Dennis S. O'Leary, M.D., President of the Joint Commission on Accreditation of Healthcare Organizations. With me today is Mr. Clifford Houser, Associate Director for Medical Technology of our Hospital Accreditation Program.

I am pleased to have the opportunity to present the views of the Joint Commission on the Federal Government's role in ensuring the quality of medical laboratory testing.

As you are aware from our prepared statement, the Joint Commission and its predecessor programs have been reviewing hospitals, including their clinical laboratories, and rendering accreditation decisions for over seventy years. The rigor and validity of Joint Commission standards and surveys are widely recognized.

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[1] See p. 297 for Dr. O'Leary's prepared statement.

Today, both the Federal Medicare Program and forty-one States accept Joint Commission accreditation as meeting their regulatory requirements in whole or in part.

Joint Commission accreditation activities now extend into five additional areas of health services delivery. These include: long-term care, home care, hospices, ambulatory care, and mental health. The establishment of a new managed care accreditation program is expected shortly.

The Joint Commission recently changed its name to the Joint Commission on Accreditation of Healthcare Organizations to reflect its expanding scope of quality of care evaluation services.

Presently, the Joint Commission accredits 5,200 hospitals and 3.100 non-hospital health care organizations. Of the 5,200 hospitals, 2,200 are also accredited by the College of American Pathologists.

As noted in the information previously provided, the Joint Commission accredits organizations, that is, hospitals, as opposed to their subset components, like clinical laboratories. Nevertheless, Joint Commission standards include rigorous standards for clinical laboratories. Joint Commission standards are considered to be optimum achievable as opposed to minimum standards.

You have requested a description of our accreditation process. This is as follows.

Drawing upon the knowledge of nationally recognized experts, standards are established. Standards of critical importance to the accreditation process are then identified and criteria for determining compliance with the standards are established.

Joint Commission surveyors usually in full-time employment are trained to survey the standards. The typical full hospital survey team includes a physician, nurse, a hospital administrator, and a medical laboratory technologist, most of whom have master's degrees and many of whom have Ph.D. degrees. The technologist is deleted from the survey team if the hospital is accredited by CAP.

Surveys of applicant hospitals are then conducted. The survey team provides a detailed report to the Joint Commission. This report then undergoes careful analysis and validation. Survey findings are presented to the Joint Commission's Accreditation Committee, the committee of the board which renders an accreditation decision. This decision may be: unencumbered accreditation, accreditation with contingencies, or nonaccreditation.

The accreditation decision and the detailed report are provided to the hospital. The hospital is provided two opportunities to resolve contingencies. Failure to resolve a contingency within the stipulated time frames will result in a nonaccreditation decision.

Evaluation of contingency resolution is determined either by an on-site review or evaluation of a written progress report, or both.

As you know, Section 1865 of the Social Security Act provides that hospitals accredited by the Joint Commission shall be deemed to meet the health and safety standards requisite to Medicare participation.

The Social Security Amendments of 1972 established a requirement for Department of Health and Human Services oversight of hospitals participating in Medicare through the Joint Commission accreditation process. This oversight involves HCFA inspection of an annual random sample of accredited hospitals, the conduct of complaint investigations of such hospitals, and an annual report to Congress concerning the outcome of these inspections.

Parenthetically, the validation sample is considerably more than one percent, as was discussed in the previous testimony. This process may be characterized as an annual Governmental assessment as to whether accredited hospitals meet Medicare's hospital health and safety standards. Based on these findings, a conclusion is drawn concerning the prudence of continuing Government reliance on accreditation for Medicare certification purposes.

Since 1973, when validation surveys were first inaugurated, the following Joint Commission/HCFA arrangements have evolved. The Joint Commission provides HCFA with schedules of contemplated hospital accreditation surveys. The Joint Commission provides HCFA with the results of the deliberations of its Accreditation Committee with respect to hospitals—that is, they are either accredited or nonaccredited.

And the Joint Commission provides HCFA with copies of accreditation reports for hospitals subjected to HCFA validation and complaint inspections.

The Joint Commission has no relationships with HCFA respecting clinical laboratories involved in interstate commerce. It is, of course, likely that from time to time an accredited hospital operating a clinical laboratory in interstate commerce will be selected for a Medicare validation or complaint inspection. In such cases, the Joint Commission would provide HCFA a copy of the hospital's accreditation report, including comments pertaining to the clinical laboratory.

Virtually all hospitals which participate in the accreditation process receive recommendations for clinical laboratory improvement. Where contingencies are involved, the Joint Commission requires verification of their timely correction as an integral of the accreditation process.

In 1986, the Joint Commission laboratory technologist surveyor participated in 893 hospital accreditation surveys. Approximately eleven percent of the accreditation decisions pertinent to these surveys resulted in a contingency being attached to the hospitals' accreditation respecting the clinical laboratory. In more than half of these instances, the Joint Commission required on-site verification of problem correction.

In 1987, the Joint Commission laboratory technologist surveyor participated in 716 hospital accreditation surveys. Approximately fifteen percent of the resultant accreditation decisions involved a clinical laboratory contingency. These contingencies were related to the following areas. Approximately one-third were in the area of laboratory proficiency testing; one-third were in the area of quality control, and one-third involved either administrative procedures or safety problems in the laboratory.

From the Joint Commission's perspective, the major quality problem in clinical laboratories and generally in quality assurance throughout hospitals and other organizations delivering care is the failure to identify significant operational problems and to take timely action to resolve these problems. These failures are a direct consequence of the current inadequacy of quality assurance methods.

In 1986 the Joint Commission launched a major set of initiatives to develop more sophisticated quality assurance methods which will focus on outcomes of care. This is a massive research and development endeavor, which is difficult to fund and to move quickly to fruition. We cannot meet the existing need alone.

If we are to achieve significant progress in clinical laboratory quality improvement, well-researched, scientifically-sound, external evaluation systems will be required for this functional area. Rapid advances in clinical laboratory instrumentation make this need even more compelling.

Increased Federal and State regulation of clinical laboratories using inadequate evaluation methods is not the answer to the problem. We frequently hear quality of care concerns being expressed by the Congress, but there is little evidence of a matching funding commitment to develop better evaluation systems.

For instance, two years ago, the Congress approved a $6 million patient outcomes research project. Eventually, only $2 million was authorized. Although other relevant research funds are budgeted for certain Federal agencies, the funding levels are modest. Annual funding of $100 million to $300 million for quality assurance research would approach adequacy.

We are keenly sensitive to the Federal budget deficit problem. But if quality of care is truly a priority of the Congress, this priority must be reflected in substance. Such a commitment would be of inestimable and immediate value both to Government oversight of clinical laboratories and to private sector external evaluation activities.

We appreciate the opportunity to present the views of the Joint Commission on this important matter.

Senator LEVIN. Thank you very much, Dr. O'Leary.

Dr. Wagner?

TESTIMONY OF LOYD R. WAGNER, M.D., VICE PRESIDENT, COLLEGE OF AMERICAN PATHOLOGISTS, ACCOMPANIED BY GUY GLENN, M.D., AND ROBERT RICKERT, M.D.

Dr. WAGNER. Thank you, Mr. Chairman.

I am Loyd Wagner, a Board-certified pathologist and Vice President of the College of American Pathologists. At the table with me are Dr. Guy Glenn, who is the Chairman of the Commission on Scientific Resources, and Dr. Robert Rickert, who is Vice Chairman of our Commission on Laboratory Accreditation.

We have submitted extensive written testimony which I would refer to, and in the interest of time, I will abbreviate even my oral statement.

Senator LEVIN. We appreciate that, and the statements will be made a part of the record.[1]

Dr. WAGNER. Thank you.

We welcome the opportunity to work with you to assess Federal and private sector quality assurance initiatives. The College of

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[1] See p. 312.

American Pathologists is a national medical specialty society representing more than 10,500 physicians who are certified or eligible to be certified by the American Board of Pathology.

Since it was established in 1947, the College has been dedicated to the pursuit of excellence in all areas of the medical laboratory. The purpose of this dedication has been to strive continually to improve the availability of quality laboratory services to the American public.

Prior to 1950, there was little availability of quality control materials and programs for the clinical laboratory to use in the measurement of performance. The process of developing quality assurance methods for the protection of patients has been evolutionary. The methods available today are the result of a continuing effort by the College and other concerned organizations, both governmental and private, to assure quality.

To assure quality and to measure laboratory performance, no single assessment technique is sufficient. A multidimensional approach is necessary to gauge a laboratory's performance. This approach involves regular use of standards to ensure test accuracy, daily comparison of quality control data, satisfactory participation in proficiency testing programs, and laboratory accreditation.

The CAP, through its unparalleled leadership role in development of laboratory improvement programs, provides laboratories with a variety of proven methods to improve performance and ultimately provide the public with quality medical care.

During the forty-year period, the College has had more impact than any other single organization on standardization and the improvement of clinical laboratory procedures. Frequently during this period, the CAP has worked on a collaborative basis with Federal and private sector organizations to realize this goal.

Through its laboratory improvement programs, the College offers challenging, cost-effective programs that are carefully designed to help laboratories provide quality patient care. Examples of these programs and the scope of the service commitment to the laboratory community include: CAP-certified Reference Materials and Standard Solutions Program; the CAP Surveys Program, which is our proficiency testing or inter-laboratory comparison program; the CAP EXCEL Program, for small laboratories, including physicians' office laboratories; the CAP Performance Improvement Program in Cytopathology; the CAP Laboratory Accreditation Program; the Forensic Urine Drug Testing Program; the CAP Quality Assurance Service for Daily Quality Control, and finally, the Commission on Office Laboratory Assessment, a program being designed for physician office laboratories.

To put the scope of these activities in perspective, it is useful to know that an estimated 3.1 billion laboratory tests were performed in the United States during 1987, including 2.2 billion tests in hospital laboratories, 336 million tests in commercial laboratories, and 529 million tests in physician office laboratories.

The College estimates that a minimum of fifteen percent of a hospital laboratory's direct costs are consumed by quality assurance activities. A recent cost accounting study at a four hundred-bed Midwest hospital revealed that twenty percent of that laboratory's annual costs were assigned to quality assurance activity.

Although clinical laboratories represent one of the most stringently-regulated segments of the health care industry, the private sector's self-monitoring initiatives in fact preceded those of the Federal Government, and today, still exceed most governmental efforts intended to foster laboratory improvement and contribute to the assurance of quality medical care for the public.

Practice of laboratory medicine, however, is not perfect. It requires the finest technological instruments available, combined with sound human judgment, based on extensive educational training of physicians and other laboratory professionals, in a continually evolving medical science.

We must monitor deficiencies constantly, whether human or technological, and raise standards as technology evolves to the highest levels achievable.

In the clinical laboratory there has been a quantum leap in the last twenty years in both what we can test for and how well we can do it. And it is largely through the diligent self-policing by the private sector that such high standards of quality and integrity have been achieved and are maintained.

Similarly, no single organization can perform the necessary monitoring. A multidimensional approach is required, involving cooperation among the private sector, Congress, and Government agencies.

The CAP has consistently worked with State, Federal and private sector organizations desirous of developing realistic, practical and achievable performance standards for laboratories.

The CAP is doing its part, as documented in data from CAP laboratory improvement programs, in commitment of financial resources and expertise to the National Bureau of Standards and other national and international standards organizations and in the sharing of proficiency testing and accreditation data with Federal and State regulatory agencies over the years.

Through the College programs and other programs offered by other professional laboratory organizations, the private sector contributes significantly to quality assurance in laboratory service.

Now Congress and regulatory agencies must do their part—not through further legislative and regulatory initiatives that would result in decreased efficiency and increased costs, but through recognition of worthy private sector quality assurance programs, appropriate payment for laboratory procedures, and the dedication of research funds for expanding definitive method development at the National Bureau of Standards and technology assessment at the Centers for Disease Control.

Such a commitment will yield far greater return in improved health care than additional burdensome laws and regulations.

We believe that the public and medicine will be far more appropriately served by the Government if it were to allocate resources to Federal agencies such as the CDC and the NBS for development of better methods and for assessing the state-of-the-art and identification of specific areas where continued improvement is warranted.

Since much of the data or mechanisms needed to obtain such data exists and is available to the Federal agencies, there is no need to create a new collection system. The Government should direct its efforts to a more productive use of assessment systems and concentrate activities toward addressing educational and technology development needs regularly identified by extent programs.

It also has been clearly demonstrated that regulatory agencies can use these private sector programs to identify laboratories whose performance requires intervention and act accordingly.

The College of American Pathologists stands ready to work with Congress and other Federal agencies to achieve our common goal of quality medical care for the American public.

Thank you, Mr. Chairman. I will be glad to answer any questions.

Senator LEVIN. Thank you, Dr. Wagner.

I am going to have to leave in about three minutes. Perhaps Senator Cohen will be back by then. If not, we will have to adjourn for a few moments. He is over voting, and that is where I have to head.

First let me ask Dr. O'Leary a question. Yesterday we heard from Mr. Bob Johnson and his attorney. Mr. Johnson's wife's Pap smears in 1978 and 1979 were reviewed at Northern Virginia Doctors' Hospital. In both years the Pap smears were classified as Class II, which it is my understanding means that they were atypical, but that there was no evidence of malignancy. It turned out later that the Pap smears should probably have been classified as Class IV in 1978 and Class V in 1979. Mrs. Johnson died of cervical cancer in 1981.

Northern Virginia Doctors' Hospital is accredited by the Joint Commission, and I believe the lab is accredited by CAP. Even though CAP did the actual lab inspection and accreditation, the Joint Commission still has responsibility for any lab in a Joint Commission-accredited hospital—at least that is my understanding.

The lab worker who reviewed Mrs. Johnson's Pap smear was a physician who was Board-certified in anatomical pathology but not in clinical pathology. In fact, she failed her clinical pathology board several times. It appeared she had very limited training in reviewing Pap smears.

Would this lab worker have met the Joint Commission's standards for lab personnel reviewing Pap smears?

Dr. O'LEARY. I think the issue is, within the framework of that laboratory, is there competence available to assure interpretation. In other words, this lab worker may not have met the personnel requirements, or at least would not have met our definition of competency to perform a certain act.

The question is whether there was access to another qualified pathologist or another individual competent to interpret the slides.

From our standpoint when we go into a laboratory, our determination is does the laboratory have access to individuals who are properly qualified and competent to make the interpretation.

Senator LEVIN. You don't have a requirement that the laboratory use persons who are qualified—simply that they have access to such persons?

Dr. O'LEARY. No; that they use them.

Senator LEVIN. So then my question comes—are you able to tell us from the information I have given you whether or not that particular lab worker would have met your standards for lab personnel who review Pap smears?

Dr. O'LEARY. I think it would be difficult without knowing a good bit more about the individual. Competency of individuals may derive from several bases. Either you have education and training relative to whatever you are trying to do, or you have definitive experience in doing it, or you even invented the skills relative to that.

Senator LEVIN. What I'd like to do is give you some additional information and have you, if you would, submit an answer to us for the record.

Dr. O'LEARY. That would be fine.

Senator LEVIN. Shouldn't we require some form of certification testing for persons who read Pap smears?

Dr. O'LEARY. Should we require certification? Well, I understand the basis of the question, but I believe there are many who take the posture that we are over-certified in a variety of ways, and there are real questions as to whether at that degree you are getting an adequate quality, legitimate quality yield out of that activity, or are you alternatively creating a protective guild.

Senator LEVIN. What is your own opinion on that question? Should we require certification testing for persons who read Pap smears?

Dr. O'LEARY. A certified Pap reader. That's the question.

Senator LEVIN. Certified testing.

Dr. O'LEARY. I think that is, in my personal opinion, an extreme that I would not like to see.

Senator LEVIN. Dr. Wagner?

Dr. WAGNER. In our accreditation program, there is a requirement that there be adequate personnel to review Pap smears; that they have adequate training, and that is evaluated each time a laboratory is surveyed by our inspection team. That qualification usually involves training in specifically cytotechnology, and I would guess that the majority of those people are certified as cytotechnologists.

Senator LEVIN. You would guess that the majority are certified—do you know what percentage are certified?

Dr. WAGNER. I do not have that information, sir.

Senator LEVIN. Could you supply us that for the record? Is that available to you?

Dr. WAGNER. I am not sure it is, but if it is available, we would be glad to make it available to you.

Senator LEVIN. Could you find out for us, if it is not available, by taking some kind of sample?

Dr. WAGNER. I believe we have information that we might be able to glean from the application packet. It may be manual, but I think we have information to that effect.

Senator LEVIN. Okay. A little earlier, you heard Mr. Hays talk about what statistical information HCFA does or does not receive from the Joint Commission and from CAP. He was not certain what information HCFA does receive, in fact.

Dr. O'Leary has told us some of what the Joint Commission provides to HCFA. What I'd like to do is just question you a little further, relative to your testimony on page 12. Do you, Doctor, supply to HCFA that information in the surveys which result in deficiencies being awarded to labs?

Dr. O'LEARY. We do not, on a regular basis, describe the contingency or deficiency.

Senator LEVIN. Okay. Now—because I have to run to vote, or else I am going to miss it—do you have any objection to providing that data, if you were asked by HCFA?

Dr. O'LEARY. I think that the issue is—would I personally——

Senator LEVIN. Object to providing it if HCFA asked you for it.

Dr. O'LEARY. Okay. I personally have no objection to that. My organization would consider that a major policy issue. But the Federal Government sets the rules of the game; we decide whether we want to play by the rules of the game, and my guess is we will play by those rules.

Senator LEVIN. Okay. We are going to have to adjourn until Senator Cohen comes back, which should be any moment.

[Short recess.]

Senator COHEN. The meeting will reconvene.

I am not sure exactly where Senator Levin left the proceedings. Dr. Wagner, had you completed your testimony?

Dr. WAGNER. Yes.

Senator COHEN. And the questions started at that point?

Dr. O'LEARY. Yes, we have had several questions.

Senator COHEN. All right. Dr. O'Leary, let me respond just briefly to one of the statements you made. There is enough fault to go all the way around in this entire matter, and Congress is not immune from criticism. Our purpose is not to engage in the pointing of fingers but to try to find some solutions to what we think is a serious problem in terms of its consequences. It may not be serious as far as the scope of the problem. But we learned yesterday when the problem hits a person—a man who is in the audience today, and he loses a young wife, leaving his children without a mother for the rest of their lives—that comes home very strongly and emotionally.

Dr. O'LEARY. We share that.

Senator COHEN. That is why we are holding hearings, not to try and point the finger at HCFA or to point it at you or CAP or anyone else, but rather to find out what needs to be done and what can be done and how quickly can we and should we do it.

One of the things we have found—you are right as far as the funding is concerned—we found, for example, that some physicians who send out lab tests may have labs that are performing these tests at fifty cents per slide, while the test is being billed by the physician at thirty-five dollars. One of the recommendations that has been made and probably will be included would be to have direct billing from either the lab or the hospital to the patient or to Medicare for reimbursement. We might be able to save some significant amounts of dollars in that case to put toward more research for ways in which we can establish better standards.

But we are looking at a $20 billion industry at this point; $20 billion is being spent on laboratory testing, forty percent of which comes out of the U.S. taxpayer.

Dr. O'LEARY. We know that.

Senator COHEN. So we have got to find a better way of spending our money as well, and perhaps redirect that toward more research and examination.

Let me turn, Dr. O'Leary, to you first on HCFA requiring annual inspections of laboratory participation in Medicare. Our understanding is that HCFA has advocated this in meetings with the Joint Commission, but the Joint Commission insists on a three-year inspection cycle.

How do you assure quality if you are only inspecting once every three years?

Dr. O'Leary. I think that is a fair question, of course raised in other contexts as well. The research and development initiatives that we are moving toward now provide amongst other things the creation of an ongoing interactive relationship involving exchange of performance data, both clinical and organizational performance data, which if effective—and we think that this is quite feasible to do—will give you a considerably more effective monitoring system than an annual inspection will.

We are probably two to two and a half, three years away from being able to implement something like that. Meanwhile, the issue of annual inspections is not something upon which we are rigid.

Our accreditation cycle is a three-year cycle. If the Federal Government wishes to change the ground rules under which the deemed status relationship operates, as I conveyed to Senator Levin just before he left, the Government sets the rules, the Joint Commission in the deemed status relationship determines whether it wishes to play by the new rules, and chances are we would be flexible on that issue.

It does have cost implications for the individual hospitals, as you understand, but that is a choice that they make—just like we make a choice, they would make a choice.

We are happy to entertain discussions along those lines or on other core deemed status issues.

Senator Cohen. What about unannounced inspections? Again, our understanding is the Joint Commission announces inspections four to six weeks in advance.

Dr. O'Leary. Well, let me take that on a couple of fronts. Number one, we do unannounced surveys, usually for cause, but we do an increasing number of them because we have some concerns about the same sort of thing that you are reflecting. Particularly if there is a problem, and they know you are coming, it is easier to sweep that problem under the rug.

On the other side of the coin, though, particularly with regard to our quality assurance standards, which is really what you are talking about in these hearings, we require careful documentation of a track record of at least a year. Let me tell you, if you have four weeks' notice that the Joint Commission is coming, trying to create even a paper track record of performance back over a year is impossible; it cannot be done. And in fact, failures on quality assurance standards, that is, noncompliance with quality assurance standards, rides up as the highest noncompliance area. If advanced notice is supposed to be helpful, it is not helping these hospitals very much. These are very, very common contingency areas.

Senator Cohen. So it would be very difficult to create a paper trail of excellence?

Dr. O'Leary. That is right.

Senator COHEN. Is there too much emphasis, in your judgment, upon paper trails as opposed to, let's say, on-site types of inspections so you can see the conditions under which the inspections are being conducted?

Dr. O'LEARY. Well, I think there are a couple of problems. Paper trail is one of the problems. The other problems are that all of us rely very heavily on examination of structural characteristics and functional characteristics, so-called structure and process standards. Those standards only define a capacity to provide high-quality care. You don't go that next step and find out whether the organization really does all the things that it is capable of and then finally looks at what the consequences were for the patient, what was the outcome for the patient.

That is what our new initiatives are all about; it is the building of an outcome evaluation into this whole process. And as that happens, the reliance on paper as such becomes reduced very significantly, and we move towards, if I can use the term, data-driven quality assurance systems, where you have a constant and pretty comprehensive computer-driven monitoring process that kicks out outliers that tell you that here may be a problem you should look at. It is a much more functionally-oriented kind of program, geared toward identifying problems fast and taking care of them.

Senator COHEN. Speaking of outcome orientation, Dr. Roper has promoted the Federal Government issuing so-called report cards on the death rates and number of health and safety violations in hospitals and nursing homes. Would a similar system used for our Nation's laboratories be called for? Should we have publishing of lab accuracy rates so that doctors could make a judgment as to which lab to send their tests to? That is outcome-oriented.

Dr. O'LEARY. Well, I guess yes, it is, but not clinically outcome-oriented. I would take it a step further, because the real issue in my mind eventually is how does the performance of the laboratory relate to the outcome of care for the patient. The outcome performance in the laboratory is a vacuum kind of assessment—very important, mind you, but if you cannot relate that back to what happens in relation to clinical care, you really have not gone the final step.

The HCFA report cards, if you will, I have problems with as presently constituted for their failure to adjust for severity of illness—no small issue—and a tendency to lead people to believe that you can look at numbers and read quality.

All of us would like to believe that is true because that would make life very simple. But there are too many variables, when you are talking about a human being called a patient. And if we are trying to draw valid conclusions about quality of care, in my humble opinion, I think you have to use data, outcome data, process of care data, to lead you to possible problems and then analyze them and solve the problems.

Now, that kind of information can be published. That is meaningful information. Data, particularly not adjusted for severity of illness, is of very limited value.

Now, if you want to come to the issue of proficiency testing and the validity of that as a measure of quality, I quite frankly would like to defer to my colleague on the left, or the one on the right, to make that judgment because they know a lot more about this than I do.

Senator COHEN. I will come to them in just a moment. What objections would the Joint Commission have in applying the Medicare independent lab standards to hospitals? Would there be any objection?

Dr. O'LEARY. Could I ask Mr. Houser to comment on that?

Mr. HOUSER. The Medicare independent laboratory standards are essentially the core standards of the Joint Commission standards at this time. In 1978, when Medicare and the Joint Commission negotiated the standards development for the Joint Commission, a great percentage of the 405, 13-405, 16-405, 17 aspects of the Medicare independent laboratory standards were incorporated in the Joint Commission standards. So basically, both the Joint Commission standards and the Medicare standards for independent laboratory are as a result of the stem standards of the 1967 CLIA standards, so they are virtually all the same.

Senator COHEN. In other words, the short answer would be you wouldn't have any objection.

Mr. HOUSER. Correct.

Dr. O'LEARY. But important to know that they are kind of the same right now.

Senator COHEN. A question on the workload standards for cytology. We had some testimony yesterday about a cytotechnologist in a Joint Commission hospital lab who was screening up to 300 Pap smear slides a day. I raise this question in view of a Joint Commission standard, and I am going to quote it, that requires "a sufficient number of qualified laboratory technologists to perform promptly and proficiently the tests required."

How could a hospital with a lab that engages in practices allowing a technician to examine up to 300 slides a day retain its accreditation?

Dr. O'LEARY. I think it is a question of whether we know that that problem--have been advised about that.

Senator COHEN. Assuming that it in fact is true, and there is a lawsuit that would demonstrate that that would be the case; the question is how could a hospital retain its accreditation under your standards, quoting from them as I just did.

Dr. O'LEARY. Assuming that that is a key standard—and I don't have the manual sitting in front of me right now—but if that were true, and that is a systemic problem—in other words, they don't have just one little, old technician sitting over here, and that's a problem—if that is something that happens on an ongoing basis, that would result in a contingency which, if not rectified within a reasonable time frame—and in this case, we would draw a pretty tight time frame—that is a problem you can correct pretty quickly, and that could lead you to nonaccreditation.

Senator COHEN. Thank you.

Senator Levin?

Senator LEVIN. Thank you, Senator Cohen, for allowing me to interrupt for just one question. I am afraid I am going to have to leave, and Senator Cohen will chair.

If you haven't been asked this question already, I'd like to just ask it of each of you. Do you think that you should consider some kind of restriction on paying cytotechs by the number of Pap smears that they review, since that practice could encourage cytotechs to review more Pap smears than can be done accurately?

Dr. O'LEARY. I'll be happy to take the first crack at that, since I am the least knowledgeable person about it. But as a physician and layperson, I have the same kinds of concerns that you do.

It doesn't mean that paying on a piecework basis is always bad. For instance, an alternative way would be to say we will pay on a piecework basis, but only up to a certain amount of pieces per unit time; we will put a cap on it. That is another way of introducing a kind of control.

Open-ended piecework arrangements in this context are dangerous, in my opinion.

Senator LEVIN. Dr. Wagner?

Dr. WAGNER. In general, I would have to agree with Dr. O'Leary that that is not a desirable situation. Certainly in our situation in the laboratories, we evaluate the workload, and if we feel that it is excessive, we will make a recommendation that the laboratory not be accredited, and we have in fact failed to accredit some laboratories that did not have adequate personnel.

Senator LEVIN. Do either one of you have a restriction on open-ended piecework, a prohibition on open-ended piecework?

Dr. WAGNER. Not per se.

Dr. O'LEARY. We don't establish standards relative to payment practices.

Dr. WAGNER. Mr. Chairman, if I may add, it is difficult to come up with a rigid number of slides or cases that an individual can screen. We believe that the workload should be reasonable, and we do not feel that they should be overloaded. But there is difference in the types of cases that personnel do evaluate. And it is very dependent upon that mix as to how much work in a day an individual can do. Most of the testing——

Senator LEVIN. I was only talking about the open-ended piecework issue; I wasn't talking about that other issue. And I think, Dr. O'Leary, it is not just the payment issue; it is a medical quality issue.

Dr. O'LEARY. But that quality issue can be identified separately from the payment issue per se. That is a workload issue.

Senator LEVIN. Thank you.

Senator COHEN. Could I just follow up what your recommendations would be with respect to moonlighters? Does that present a problem in terms of the quality of tests if somebody works eight hours in one job and shows up at six or seven at night and puts in four or five hours when they are tired?

Dr. O'LEARY. The moonlighting issue is a worrisome issue, and it has surfaced in other areas, such as residency work, and is an issue that we are just now starting to open up for examination from a standards standpoint.

Oddly enough, I guess, that issue has not surfaced as a standards issue or a quality of care issue in the past. That doesn't mean it shouldn't have. It just hasn't. We are now examining the issue, broadly, not just in the laboratory, but residents, and so on and so forth.

Senator COHEN. We have evidence that many of the lab tests are done during the evening hours, and yet most of the inspections are conducted during the daytime. Does that lead you to call into question the nature of the inspections themselves?

Dr. O'LEARY. No, that doesn't bother me per se as long as—well, either way. If there is documentation of the laboratory results, there is an ability to assess the quality of those results without being over the shoulder of the technologist as the procedure is being performed, which would lead you to draw a conclusion as to whether the services being provided are good or not on the night shift or on the graveyard shift, for that matter.

I think that you can make valid determinations, particularly with more data-oriented quality assurance systems, and not require a physical presence, which may or may not give you an answer about the adequacy or the quality of the work being done.

Hanging over somebody's shoulder is not necessarily the right answer to that evaluation.

Senator COHEN. Dr. Wagner, in your testimony you indicated that CAP doesn't agree that PT results represent the best a lab can do.

Dr. WAGNER. That is correct.

Senator COHEN. Why is that so, sir?

Dr. WAGNER. Proficiency testing is the testing of an event in time, and it simply reflects what that laboratory did on that particular situation. It is one of the measures of laboratory quality, but it cannot be utilized alone to assess whether or not a laboratory is performing quality work.

There are other things like daily quality control, space, other activities that go along with that, that better assess quality.

Senator COHEN. What about on-site proficiency testing? Is on-site PT a better measure of lab performance than PT done through the mail?

Dr. WAGNER. On-site proficiency testing—and I presume you mean something carried into the laboratory—we do not feel is any better method of assessing quality than a mailed-in sample in general. Yet it is difficult, for instance, to not identify in the laboratory that that is truly a proficiency test sample. So therefore, it would probably be the natural thing on cytology, for instance, for a cytotechnologist to slow down and look at that more carefully.

On-site carried on has some problems in the general proficiency testing area of stability of specimens and that type of thing, and we do not feel that that adds much to what is done with the mailed-in sample.

Senator COHEN. What about blind testing?

Dr. WAGNER. Blind testing again is a very difficult thing to institute. First of all, if you are talking about blind testing in a laboratory situation, you have to talk primarily about a blood sample. There are real stability problems in doing that. You also then have to introduce that into the laboratory in a method that it will not be realized as a blind sample by your laboratory technologist, which means it means a patient identification. That then raises the issue that that result could accidentally go out on someone if you put it into the workload. And there are problems with blind proficiency testing that we feel negate the advantages of it.

Senator COHEN. Dr. Wagner, we heard a number of criticisms about CAP yesterday. I want to review just a couple of them with you and get your comments for the record.

The criticisms include that the voluntary inspectors in CAP are untrained, do not talk to the people who do the tests, are not accountable for the results of their inspections; that CAP inspection now emphasizes administrative structure and organizational charts rather than quality control; that deficiencies identified by the technologist team member are deleted or altered by others in the final report, and that CAP lacks sufficient numbers of inspectors to perform inspections on its two-year cycles, being anywhere from three to nine months behind on many inspections; and finally, that an organization of pathologists has conflicts of interest in inspecting labs that are directed by non-pathologists.

Would you care to comment on any one of those?

Dr. WAGNER. Well, I hope, Senator, I can remember all of the various parts, but I will try.

Senator COHEN. I will give them to you for the record and get your comments.

Dr. WAGNER. Fine. I would like to address those as best I can, sir.

First of all, the inspection of our laboratories is accomplished by volunteer inspectors. There are requirements for those individuals. First of all, that inspector is always a pathologist. That inspector is always from a laboratory that is accredited under the Laboratory Accreditation Program.

The team that is put together by the inspector will vary depending on the size and the complexity of the laboratory to be inspected. It will ordinarily involve other pathologists, other doctoral scientists, other technologists who are knowledgeable in an area to be inspected, and that team is usually then tailored to the needs of the individual laboratory.

Those teams will vary from one or two people for one to three days up to as many as thirty-six going into an operation to inspect it. They look at all areas. They look at all of the information. They are trained inspectors. They have to go through a training program or have been members of a team before. And we simply do not feel that our inspectors are inadequate.

Senator COHEN. If you were going to conduct an inspection of a cytology lab, would you use a cytotechnologist or cytopathologist in conducting that inspection?

Dr. WAGNER. Yes, we would.

Senator COHEN. If you were to use someone who did not have that background, would that lead to an inadequate inspection result?

Dr. WAGNER. Most of the time, if you have a laboratory that has an extremely high volume of cytology, that team would usually be put together with a knowledgeable cytotechnologist and/or cytopathologist as a member. If there is an average amount of cytology in the laboratory—for instance, the hospital setting almost routinely, I would say without exception—that inspection would be carried out by the pathologist leader of that team.

Senator COHEN. If it were not carried out by a cytotechnologist or cytopathologist, would that be an inadequate inspection in your judgment?

Dr. **Wagner**. I believe that an ordinary pathologist has sufficient training that he could look at that—even though he is not specialized in cytopathology, would be competent in making that inspection. I would not feel comfortable, Senator, if the ordinary medical technologist who does not have experience in that area would inspect that area.

Senator **Cohen**. So what you are saying is a general pathologist would be competent to make an examination for inspection purposes of a cytology lab?

Dr. **Wagner**. Yes, following the guidelines that are present in our system.

Senator **Cohen**. What about the cytotechnologist screening two to three hundred slides a day; do you have a position on that?

Dr. **Wagner**. Obviously, Senator, that sounds extremely high in number. As I started to say before——

Senator **Cohen**. Not "sounds"—it is, isn't it?

Dr. **Wagner**. I would say yes.

Senator **Cohen**. Are you behind roughly anywhere from three to nine months on inspections?

Dr. **Wagner**. Senator, we do not believe that that is true. If you have specifics, we will be glad to get the information back. But after the completion of all of the paperwork that is necessary and the preliminary, there would be an average delay of about ten to twelve weeks probably from the time all the work is completed until the inspection accreditation process has been completed.

We do not believe we are that far behind.

Senator **Cohen**. So your testimony is that the maximum you are would be ten to twelve weeks?

Dr. **Wagner**. Yes.

Senator **Cohen**. And the suggestion of three to nine months is without substantiation?

Dr. **Wagner**. That is correct. If you have specifics, we would be glad to investigate them and check them.

Senator **Cohen**. Would you agree, especially in the field of cytology, that three to nine months is a lifetime for the women in question?

Dr. **Wagner**. It certainly can have an impact, yes.

Senator **Cohen**. I have some more questions, Dr. O'Leary, but we are running a bit behind time, so I am going to submit several questions to you and Dr. Wagner and ask for your response in writing, I thank the panel for coming this morning.

Dr. **O'Leary**. Fine.

Dr. **Wagner**. Senator, may I correct one thing? The statement was made by the Chairman earlier that Northern Virginia Hospital was inspected by CAP. Our information is that it has not been inspected and was never accredited by CAP. I would like that on the record.

Senator **Cohen**. Does it follow that it was accredited by the Joint Commission?

Dr. **O'Leary**. The hospital was accredited by the Joint Commission in 1978.

Senator **Cohen**. And if the hospital is accredited and there is a lab within it, how does that work, Doctor?

Dr. O'LEARY. If the laboratory is within the hospital and it is accredited, it is accredited. If the laboratory has a contingency and that contingency is not resolved, it can bring the whole hospital accreditation down.

We did not have a contingency system operative in 1978. The system has changed and tightened considerably since that time. That is ten years ago.

Senator COHEN. But it would follow that if at that time the hospital was accredited, the lab within the hospital also would have been accredited.

Dr. O'LEARY. That is correct.

Senator COHEN. Thank you very much, gentlemen.

Next, we have a panel of witnesses including Harry Groome, President of the American Clinical Laboratories Association, accompanied by Dr. Edward Kaufman; and Mark Birenbaum, Ph.D., Associate Administrator, American Association of Bioanalysts.

Gentlemen, if you could summarize your statements, we have one more panel to go and do have to conclude relatively soon. If you could summarize as best you can, your full statements will be included in the record.

TESTIMONY OF HARRY GROOME, PRESIDENT, AMERICAN CLINICAL LABORATORY ASSOCIATION,[1] ACCOMPANIED BY EDWARD KAUFMAN, M.D., VICE PRESIDENT FOR SCIENTIFIC AND MEDICAL AFFAIRS, ACLA

Mr. GROOME. Senator Cohen, I am Harry Groome, and I am President of the American Clinical Laboratory Association, ACLA, and President of Smith, Kline Bioscience Laboratories, which is the clinical laboratories division of Smith, Kline, Beckman Corporation.

I have asked Dr. Edward Kaufman, who is the VP for Scientific and Medical Affairs for ACLA, to join me today to help me in answering any of your more technical questions and also to provide a pathologist's perspective.

As you suggest, I will summarize our formal statement now.

ACLA is an organization that includes the Nation's largest regulated clinical laboratories as well as some of the smaller ones. Founded in 1971, the Association's member laboratories account for the great majority of laboratory work performed in interstate commerce in the country.

We are testifying today because there is an absolute obligation that the American people be assured that when a medical test is performed, it will be performed properly, competently and accurately. That right should be insured whether the test is performed by a major clinical laboratory across town or across the State line, or whether it is performed by the patient's physician in an adjacent room.

People do not have that assurance now. Although independent laboratories and hospital laboratories that perform tests for Medicaid or Medicare patients must be Federally-certified, laboratories operating interstate, doing work only for private patients, are not.

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[1] See p. 331 for Mr. Groome's prepared statement.

This includes all unregulated laboratories, physician office laboratories, clinics, emergency care centers, and some independent laboratories.

Most patients have no way of knowing where their tests will be done. They probably do not know whether the laboratory is certified and certainly don't know the skill level of the technicians performing the tests.

We are therefore going on record to support Congressional action calling for Federal regulation of clinical laboratories across-the-board. Before any laboratory, whether in the doctor's office or in a distant State, can do any work at all, it should be required to demonstrate its proficiency through participation in a mandatory quality assurance program.

The standard should be consistent through the Nation and the resources necessary to enforce the standard should be appropriately funded.

Is medical testing valuable? Indisputably. We can screen for and detect critical illnesses months before they might otherwise become evident. We can diagnose illnesses by measuring substances like hormones in trillions of parts. We can assist and monitor treatment by measuring therapeutic drugs.

Precisely because this discipline is so refined, it is open to criticism. There are nearly two thousand tests available today in the medical community, and every one of them provides detailed quantitative information, yes or no answers, levels in measures and readings. It is this ability to measure so precisely that allows us to evaluate our performance. Because this field of medicine is mostly objective, we can see the effective changes made in any level and then go on to apply new research to increase the accuracy and advance the technology.

Perhaps no other discipline in our society gives such precise information for such a variety of human conditions, and that is why, as an industry, we need to aim for the most steady, accurate, reliable performance. There need to be standards, the highest standards, adopted, monitored, funded, enforced and maintained by everyone, big laboratories, small laboratories, home laboratories, doctors' laboratories, hospital laboratories.

If we can offer an answer, we should have a system that ensures that it is the right answer, time after time.

There is no inventory in this business. Each test result stands alone. So we are calling to bring all testing in all kinds of laboratories up to the highest level. It seems to us the only feasible way to do this is with Federal regulation, supported by a network of State and private participation.

Therefore we offer one primary recommendation, and that is: The U.S. Congress should enact a law requiring the establishment of a mandatory quality assurance program extending to all testing facilities. All clinical laboratories should be subjected to Federally-mandated and enforced, uniform, comprehensive quality-assurance regulations. Those regulations should include the following general requirements.

All laboratories should be inspected at least once annually, and those inspections should be unannounced. All laboratories should participate successfully in a Federally-operated, sponsored or approved mandatory external proficiency testing program that uses a nationally-developed uniform grading system.

All laboratories should utilize internal quality control practices covering the testing process, validation of that process, recordkeeping, corrective and preventive maintenance of equipment, instruments and facilities, and proper storage and labelling of such supplies as reagents and kits.

And finally, all laboratories should employ only those personnel who demonstrate the requisite educational background. ACLA proposes that we have stringent personnel qualifications for laboratory staff at all levels.

In contrast, there are pressures today to qualify laboratory personnel only at the most senior levels, ignoring those who actually perform the tests. Quality begins at the bench.

No one is implying that unregulated laboratories intentionally lower their quality. We do know, however, that the standards vary, the results vary, and accuracy varies. Quality depends on skilled staff and well-maintained instruments and materials.

We also recognize that there must be a balance between the economics and quality control. Quality costs money.

Medicare fee schedules must remain where they are. To slash them further would jeopardize quality testing. Clinical laboratories are the only health care provider group that has been subject to payment reductions consistently year after year.

In conclusion, we suggest that we bring everyone up to the highest standards. The technology is there to produce accurate, reliable answers. The people are there to manage the process. Let's fix the system to enable that all participants perform at the same high levels.

Thank you

Senator COHEN. Thank you very much, Mr. Groome.

Dr. Birenbaum?

TESTIMONY OF MARK S. BIRENBAUM, PH.D., ASSOCIATE ADMINISTRATOR, AMERICAN ASSOCIATION OF BIOANALYSTS, ACCOMPANIED BY NICHOLAS T. SERAFY, JR., ASSOCIATE DIRECTOR, PROFICIENCY TESTING SERVICE, AAB

Dr. BIRENBAUM. Thank you, Mr. Chairman. We will do our best to summarize our comments and will submit our complete statement into the record.[1]

Before I begin my comments, I want to thank you and Senator Levin and your staff for the professional manner in which you have approached this hearing. We believe that the completed record will reflect the quality and balance of your approach.

I am Dr. Mark Birenbaum, Associate Administrator of the American Association of Bioanalysts. AAB is an organization representing directors, managers, supervisors, and owners of small- to medium-sized independent community clinical laboratories across the United States.

To my left is Nicholas Serafy, Jr. Mr. Serafy is Associate Director of AAB's Proficiency Testing Service.

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[1] See p. 353.

Mr. Chairman, I think the point needs to be emphasized that there are three distinct types of clinical laboratory services. The first is clinical laboratory procedures, which provide information to physicians to assist them in diagnosing, treating and monitoring patients. Clinical laboratory procedures constitute part of the physicians' armamentarium in dealing with health matters, but by themselves, clinical laboratory procedures do not usually determine a diagnosis.

The second is anatomic pathology laboratory procedures, which usually require visual observation of human cells or tissues to determine the presence or absence of cancer or genetic abnormalities.

Anatomic pathology laboratory procedures can establish a diagnosis by themselves, and therefore, these procedures require the services of a physician specialist, namely, a pathologist.

The third type of service is blood banking, which we consider the procurement and storage of blood or blood products for the purpose of providing blood transfusions.

In your examination of laboratory quality issues, there must be a clear understanding of the distinction between these three types of laboratory services.

It must be stressed, Mr. Chairman, that every laboratory procedure has an inherent level of accuracy, and no laboratory procedure can be made one hundred percent accurate. In general, techniques requiring a subjective interpretation by a laboratorian are less accurate than quantitative chemical analyses or automated procedures.

When judging the performance of clinical laboratories, one must remember to consider the technological state of the art of each procedure.

Also important is the degree of accuracy required by the physician, which we term clinical relevance. A number of clinical laboratory procedures already have a higher degree of accuracy than is needed by the physician.

We are pleased to advise the Committee that, based on our analysis of proficiency testing data over a number of years, AAB believes that the quality of clinical laboratory testing in Medicare-certified or CLIA-licensed laboratories is generally good. The quality of clinical laboratory testing in Federally-unregulated laboratories, of which the overwhelming majority are in physicians' offices, is not as good as in Federally-regulated laboratories.

Therefore, we believe the Federal regulatory system has definitely had a positive effect on improving clinical laboratory performance, but it would benefit from a number of improvements, such as making the regulations uniform and applicable in all laboratory settings, establishing a uniform proficiency testing program and grading system, and improving enforcement of Federal standards.

Physician office laboratories should also be required to meet Federal standards, and in light of the testimony presented to this Committee, AAB does not understand why Federal regulation of physician office laboratories does not become effective for nearly two more years.

Quality control, proficiency testing, inspections, recordkeeping and personnel requirements are all necessary to assure quality laboratory performance. We especially emphasize the need for competent, qualified personnel at all levels and at all stages of the laboratory testing process. Specimen integrity is critical, and many errors are made before the specimen reaches the laboratory.

Physicians and their employees who procure specimens must be held accountable for these errors and be subject to personnel requirements. We caution, however, that the personnel requirements should not be overly restrictive and that alternate routes to formal college credit requirements must be included.

We feel it is unfortunate, Mr. Chairman, that while this Committee holds these hearings on quality issues, a major component of laboratory personnel standards is being legislated out in the catastrophic health insurance legislation now in conference committee—and by that, we are specifically referring to the authority of the Secretary of HHS to administer proficiency examinations for medical technologists and technicians.

Private accrediting agencies play an educational role in improving laboratory performance, but the Federal Government should not abrogate its regulatory enforcement authority to these agencies. Private agencies have demonstrated that they can efficiently provide certain services, such as proficiency testing, and the Federal Government should utilize the input and expertise of these private agencies in determining the content of, and grading criteria for, a uniform proficiency testing program.

Finally, financial incentives to physicians, including self-referrals and discounts from large hospital and corporate laboratories, are unnecessarily increasing the utilization of clinical laboratory services. Over-utilization is the key element in controlling laboratory costs to the Medicare program, and it also increases the risk of laboratory inaccuracies contributing to the mistreatment of the patient public.

Mr. Chairman, we appreciate the opportunity to share our comments with you and the Committee on the role of the Federal Government in ensuring the quality of clinical laboratory testing, and we would be glad to answer any questions you may have.

Senator COHEN. Thank you very much, Dr. Birenbaum.

Dr. Kaufman, did you have anything you wanted to add?

Dr. KAUFMAN. I have no formal statement, thank you.

Senator COHEN. You don't wish to step into the breech and volunteer any comments?

Dr. KAUFMAN. I will respond to some questions, I presume; thanks.

Senator COHEN. All right. Thank you.

Mr. Groome, critics of the CDC's proposed uniform grading system for proficiency testing have indicated it is too lenient and it would allow for marginal performance to continue under Medicare or CLIA. Would you recommend a stronger standard or grading system?

Mr. GROOME. What we are recommending is a Federally-mandated quality assurance program that would require laboratories to have their own internal proficiency testing programs and participate in an external proficiency testing program.

I think what we would like to see is a group get together to develop what those standards should be, and then make a recommendation to the Congress.

Senator **Cohen**. Dr. Birenbaum?

Dr. **Birenbaum**. Mr. Chairman, we have been running some numbers as to how the CDC standards would apply with our proficiency testing data, and to us it indicates that in some cases there may be an unusually large number of laboratories that would not comply. It is not clear to us at this time as to whether those standards would allow marginal laboratories to comply or be either too lax or too restrictive.

Senator **Cohen**. There has been some testimony describing how laboratories put their best people to work on PT samples, and then they confer with other labs to compare their results. How effective is proficiency testing if this occurs, putting your best people on it, comparing results? Does that produce an effective oversight mechanism when you have that kind of proficiency testing?

Mr. **Groome**. I am not aware of the practice. But it does talk to the necessity for blind proficiency testing, which we advocate.

Maybe Dr. Kaufman could——

Senator **Cohen**. How feasible is that? We have heard witnesses this morning say that is just not feasible.

Mr. **Groome**. In my opinion, I think it is feasible. And I think although there are some reservations associated with it that were expressed this morning, that blind testing outweighs those reservations, and it should be part of a proficiency testing program.

Senator **Cohen**. Dr. Kaufman?

Dr. **Kaufman**. I can speak for our company, where we know that it is feasible, because in 1987, we submitted some fifty thousand blind challenges to our laboratories and use it as an ongoing part of our quality assurance program, and have done so for a number of years.

So I strongly support blind proficiency testing. I think it is very feasible.

Senator **Cohen**. Dr. Birenbaum?

Dr. **Birenbaum**. I think I will let Mr. Serafy address that issue.

Mr. **Serafy**. Your first question about people putting their best foot forward for proficiency testing samples—we have seen some of that take place, and there are other laboratories that feel that this should be treated as a normal patient specimen and follow that procedure.

If you are comparing data in proficiency testing, you compare data laboratory-to-laboratory, and if you are comparing everybody with their best foot forward and still have outliers, you are on an even keel. Do you follow my direction?

Senator **Cohen**. Yes.

Mr. **Serafy**. They are supposed to treat it as a patient specimen, but in any test, everybody tries to do their best.

You earlier spoke about on-site PT. People are still going to put their best foot forward with on-site proficiency testing.

Senator **Cohen**. With unannounced inspections.

Mr. **Serafy**. Right.

The blind proficiency testing, internally, the way Smith, Kline says they have done it, it may be possible. As an external proficiency testing program, we don't feel that it is feasible. The logistics, I don't think can be accomplished in an external program at this point.

Senator COHEN. Mr. Groome, in the cytology area, would your members support a requirement that labs document workloads for each cytotech and impose mandatory workload limitations?

Mr. GROOME. Yes.

Senator COHEN. What about part-time help or moonlighters?

Mr. GROOME. ACLA is opposed to moonlighting.

Senator COHEN. Now, you advocate extending the standards to all labs, be they in the hospital, independent, or in the doctor's office.

Mr. GROOME. That is correct.

Senator COHEN. Yesterday we had some testimony that indicated that we are using the wrong standard—namely, the five thousand tests performed during the course of the year shouldn't be the standard, but rather the nature and the complexity of the test itself.

Should we, in trying to fashion Federal regulations, try to discriminate or distinguish between the complexity of tests in setting these standards, as opposed to having a numerical limitation?

Mr. GROOME. Well, on the numerical aspect, I don't think it is a matter of numbers. I don't think it really makes any difference whether a laboratory does five thousand tests a year or five million; I think the issue is quality and proficiency.

Consequently, there should be regulations that ensure that the quality of any laboratory is of the highest standard. So I don't think it should be limited by number.

Senator COHEN. All right. Any disagreement in the panel?

Dr. KAUFMAN. No. I agree with that. I think to focus on five thousand is probably inappropriate, and it would be much better to focus on the nature of the test and the context in which it is used. That means structuring a system which is much more complicated, I think, at the beginning, but in the end, it is probably easier to implement.

Senator COHEN. Dr. Birenbaum, one other question. In your written statement, you indicate that HCFA enforcement is lax, and it varies from region to region and State to State. Do you want to give us just a couple of examples?

Dr. BIRENBAUM. Well, Mr. Chairman, we provide proficiency testing data to the State agencies that we understand are operating under the observation of the HCFA regional offices. And as I understand, in all the years that we have been doing this, we have only been approached once by an HHS regional office, asking us for the identities of those laboratories that have been deficient for at least two consecutive quarters. That indicated to us that only one region was actually surveying the State agencies to see what they were doing in terms of following up deficiencies.

As far as the State-to-State, I think I'll let Mr. Serafy comment on that.

Mr. SERAFY. Well, where State licensure is in effect, there are States that will superimpose their own regulations that are stricter than HCFA regulations on the laboratories, and there is variation from State-to-State in that area.

Senator COHEN. One final point. How would you recommend the Federal Government act to regain its enforcement authority as far as deemed organizations are concerned—the Joint Commission, CAP? Who has the enforcement authority as far as your industry is concerned?

Dr. **Kaufman**. It seems pretty clear from this morning's testimony that it isn't very clear. I think there is a big role for a group like the College of American Pathologists to play. They have a very comprehensive program; it is uniform, it is highly regarded. Clearly, there needs to be a better line of authority between whichever Federal agency decides to take control and deemed organization.

Senator **Cohen**. Gentlemen, thank you very much. We have additional questions that we will submit to you, and I hope we can get your answers for the record.

We appreciate your patience and I am sorry we are running over time.

We have one final panel, Drs. Smith and Kroger, to appear before the Subcommittee.

Dr. Smith and Dr. Kroger, if you could both summarize your testimony briefly, I will ask you a few questions and we can conclude this morning's hearing.

TESTIMONY OF WILLIAM R. SMITH, M.D., PRESIDENT, AMERICAN SOCIETY OF INTERNAL MEDICINE,[1] ACCOMPANIED BY STEPHEN KROGER, M.D., MEMBER, ASIM BOARD OF TRUSTEES[2]

Dr. **Smith**. Senator Cohen, because of the time, you can be assured that we will be very brief.

My name is William R. Smith. I am a practicing internist from Enid, Oklahoma. I am President of the American Society of Internal Medicine. With me is Stephen Kroger, M.D., Chairman of the Commission on Office Laboratory Assessment and Member of the American Society of Internal Medicine's Board of Trustees. Dr. Kroger is also in private practice in Longmont, Colorado.

I think a good place to start today's discussion might be to share with you some basic principles we, as practicing physicians, physicians who are interested in the care of our patients and the quality of that care, believe are useful in discussing quality laboratory testing.

First, the American Society of Internal Medicine believes, and believes strongly, that all laboratories including physicians' office laboratories should participate in appropriate quality assurance activities. This should include, but is not necessarily limited to, participation in an approved proficiency testing program.

Secondly, we physicians in the American Society of Internal Medicine believe that there is an appropriate role for the Federal Government in promoting participation in quality assurance programs.

Although the Federal Government should acknowledge the historical commitment of the medical profession to voluntary quality assurance programs, ASIM also believes that the country has moved beyond the point where quality assurance can or should be left to voluntary initiatives alone. The stakes are simply too high to expect that the public is willing to rely solely on voluntary programs.

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[1] See p. 371 for Dr. Smith's prepared statement.

[2] See p. 376 for Dr. Kroger's prepared statement.

The third principle is that Federal regulation of physician office laboratories should build upon those programs that have been successful in the private sector, rather than reinventing the wheel or imposing an entirely new and inappropriate level of regulatory activity.

Dr. Kroger will be sharing with you in a few moments ways that Federal regulation could build upon effective private sector quality assurance programs and initiatives.

The fourth principle is that physicians' office laboratories provide an important service to patients that must be recognized and that must be preserved under any Federal policy that promotes quality assurance. We have had a private office laboratory for some twenty-five years in our office, and I would be glad to relate some of the experiences that we have had.

But it must be remembered that office laboratories are in scope anywhere from full-service laboratories to the physician who only does a dipstick on urine. We think this must be preserved.

ASIM is extraordinarily concerned about the provision enacted as part of the Omnibus Budget Reconciliation Act of 1987, which could result in the imposition of the Medicare Standards for Independent Laboratories on many or most physicians' laboratories.

Most physician office laboratories could not afford the expense required to comply with independent laboratory standards. Consequently, imposition of these standards would force them to cease operation or discontinue services to Medicare patients, thus depriving our patients of many of the benefits that they now obtain from in-office testing. These benefits will be described in detail in our written testimony.

With this introduction, I have asked Dr. Steve Kroger to describe for you the ways that existing quality assurance programs could serve as the basis for Federal policy toward physicians' office laboratories.

Senator COHEN. Thank you.

Dr. Kroger?

Dr. KROGER. Thank you, Dr. Smith.

Senator Cohen, as explained in our written statement, ASIM has a long history of supporting voluntary programs to assure quality in physician office testing. Since 1973 we have sponsored the Medical Laboratory Evaluation Program, a proficiency testing service to help physicians evaluate and improve their own laboratory performance and take appropriate corrective action.

ASIM believes that the MLE program and other similar proficiency testing programs have served as excellent benchmarks for physicians to evaluate the quality of their own in-office laboratories.

The Society strongly endorses requiring all laboratories to participate in an approved proficiency testing program.

More recently, we have joined with the American Academy of Family Physicians and the College of American Pathologists in the development of the Commission on Office Laboratory Assessment, or COLA, a voluntary educational and accreditation program for physician laboratories.

Enrolled laboratories would be required to meet several important standards in order to obtain and maintain COLA accreditation, including standards that require laboratories to maintain sufficient space, equipment and supplies needed to assure accuracy, provide assurance by the physician laboratory director that laboratory personnel have adequate training to conduct the work of the laboratory, and to implement an internal quality assurance program to assure that the reliability and medical usefulness of the laboratory data is preserved.

Compliance with standards would be determined by a careful review by COLA staff of questionnaires, check lists and documentation that would be completed and submitted by enrolled laboratories. Standards and review procedures are described in detail in our written statement.

Not mentioned in this statement, however, is the presence of onsite inspection for selected laboratories that would require on-site inspection, and every laboratory that would achieve COLA status.

Although COLA was intended as a voluntary program and is not yet fully operational, ASIM believes it is appropriate for Congress and the Department of Health and Human Services to consider requiring all physician office laboratories to obtain accreditation through a program such as COLA.

Since COLA also requires enrolled laboratories to participate in an approved proficiency testing program, mandated COLA accreditation would meet the objective of assuring that all laboratories participate in proficiency testing.

This approach to Federal regulation of physician office laboratories would clearly meet the principles outlined by Dr. Smith at the beginning of our testimony. It would assure that all physician office labs demonstrate a strong commitment to quality assurance. It would build upon successful models and programs in the private sector, while acknowledging that the Federal Government has an appropriate role in assuring that physician laboratories participate in such a program.

It would at the same time, however, allow patients to have continued access to quality testing in their own physicians' offices.

For these reasons, ASIM strongly urges this Committee to exercise leadership to promote such a Government/private sector partnership to ensure quality as an alternative to either requiring physician office labs to meet the same standards as independent labs, or to leaving quality assurance entirely up to the voluntary sector programs alone.

I would like to conclude with a brief comment on another issue that is often neglected in the debate over quality of laboratory testing.

In searching for ways to improve the reliability of testing, it is often forgotten that accuracy is not the only measure of the clinical utility of a test—that is, how the physician uses a test in diagnosing and treating patients. While a test result must be sufficiently accurate for decisionmaking, it should also be readily available to the physician and cost-effective to his or her patient. An office lab can provide immediate results. It can also eliminate the financial burden of time, travel and return visits to the physician for interpretation of the results; and it can reduce the physical burden on the elderly and infirm by providing the service on-site.

This degree of personal service to the patient and the immediate clinical feedback to the physician is lost to a great extent whenever an outside laboratory is used.

Senator Cohen, Dr. Smith and I would be pleased to answer any questions.

Senator COHEN. Thank you very much, Dr. Kroger.

Let me first turn to the issue of why it is that so few POLs now participate in voluntary proficiency testing?

Dr. KROGER. That is an excellent question, and we would like to know the answer to that ourselves. We think that many physicians don't realize the advantages to using a proficiency testing program.

Senator COHEN. What assurance do you have that most physicians would be willing to participate in such a program if you had it on a voluntary basis or through COLA? By the way, we have had quite an education in acronyms since I have been here. We have had ASIM, CLIA, HCFA, CAP, and now COLAs. I hope it has not been too confusing. But why should there be any real confidence placed in the notion that there will be voluntary compliance with a COLA approach?

Dr. KROGER. Senator, we share your concern about that, and that is the reason that we are here saying that an approach such as this should be mandated.

Dr. SMITH. Senator, one of the principles that I elucidated was that we do not feel that voluntary programs are viable any longer and therefore they should be mandated by law.

Senator COHEN. ASIM advocates that the Federal Government work through COLA to regulate POLs. One COLA requirement makes the physician responsible for making sure there are enough people with adequate training to conduct the work in the lab. Yesterday Dr. Fischer testified that physicians who run office labs do not think of themselves as lab directors or of what they are doing as laboratory work. He and Ms. Worrest—I think she is here today; I think I saw her in the back of the room—she pointed out that physicians receive little laboratory training. So I have two questions: How can physicians be expected to decide how many personnel with what sort of training they need to operate their own labs; and number two, how can these physicians be expected to appreciate the importance of daily quality control and other lab procedures since they are not particularly trained in that field?

Dr. KROGER. Senator, we don't have compelling evidence that there is a major problem in physician office laboratories. We are concerned enough, however, to approach the problem in the direction that we have, that is, mandated proficiency testing as a measure of outcome of a particular laboratory.

The physician office laboratories are a very heterogeneous group; they range all the way from single physicians to multi-specialty clinics. The degree of complexity of testing in these various offices is tremendous. To apply a single standard to a physician office where simple testing is done and to an office where complex testing is done, I think is very difficult. That is why we think that physicians first of all need to become more educated about laboratory testing; they need to develop the attitude of being a physician laboratory director.

Senator COHEN. Are you concerned about the statements made about physicians doing Pap smears in their own labs?

Dr. SMITH. I am not aware of physicians who read Pap smear slides in their own labs, unless they are trained in cytotechnology. I don't know of any physician's laboratory that does that, Senator.

Senator COHEN. Well, we have had testimony to that effect, that it is increasing on a fairly substantial basis.

Dr. KROGER. We would certainly not support any physician processing that type of test unless he was specifically trained for it.

Dr. SMITH. That would be very poor quality.

Senator COHEN. You have testified that several doctors would have to stop testing in their offices if they had to comply with Federal regulations due to the cost of complying with the standards. There are some thirteen States that currently regulate POLs. Do you have any evidence that these people have been put out of business as a result of the State regulation?

Dr. SMITH. Let me state that at least in some States, there is a tiered program of regulation of those physician office laboratories. Realizing that not all physician office laboratories are full-service laboratories, and that the amount of work done in those laboratories is very significant, as Dr. Kroger pointed out, I think we should insist that the quality of those tests that are done be excellent. But to impose an on-site testing program, the regulation that a physician have at least two years of laboratory experience before he is able to do dipsticks on urines in his office, we think is not reasonable and will affect patient care.

Senator COHEN. Well, Doctors, I have some other questions I will submit to you for the record. I just want to make a couple of observations as we conclude today's hearings.

None of us sitting up here have the answers. What we are searching for is the degree that we have a problem, and we have at least one witness who testified yesterday who has had to undergo one very, very severe personal and traumatic experience that will not be forgotten during his lifetime or that of his children. And that is what tends, I think, to get lost during the discussion about statistics. A good deal of it has to do with statistical analysis, and yet we are talking about some three billion tests being administered. And if there are errors ranging from ten percent to twenty percent or thirty percent in the course of those tests, it can translate rather dramatically in terms of human tragedy.

One of the problems we have is that we go to you as doctors; we rely upon your reputation for education and for skill and integrity. You in turn make your examinations, order certain tests to be done, and you may ship them out to a hospital or an independent laboratory, relying on their reputation and integrity and skills;. Ultimately. you get those tests back and you read them or the results. You communicate to your patients and you prescribe a certain procedure, which may be an incorrect one because of a test that was faulty; and then you have a personal tragedy.

Where is the oversight? Who is watching this system, to make sure that we minimize the risk of error, which is always going to be there? As we heard today, we don't know who that is, exactly. We don't know where the real oversight is coming from. It is not coming from Congress. It may not be coming from HCFA, because it has been delegated. It may not be coming from the Joint Commission or from CAP. So we don't know exactly where the effective oversight is coming from. And to the extent that Congress has contributed to this problem, we have to make some corrections.

When you are dealing with laws and you make a mistake in a courtroom, you can get a re-trial and re-hearing; you can appeal the process. If you make a mistake here in Congress, we can pass an amendment to correct our mistakes. If you make a mistake in the field of medicine or in that of laboratory testing, that mistake may be forever. Those are the life-threatening dimensions that are involved in this, and this is why there has been so much interest in this particular subject matter.

I want to thank you who have come before the Committee today and all of the other witnesses. I especially want to thank Senator Levin, who arranged for these hearings and really showed a tremendous interest in trying to come to grips with the problem.

I want to pay particular compliments to Mary Gerwin, Kim Corthell, and Sharon Ward—Sharon is from GAO, and Kim and Mary are my staff for this Subcommittee—for the tremendous amount of work they have invested in this, working with you and trying to secure information that we can put together in a report which will be the basis for corrective legislation.

So gentlemen, thank you very much for your patience. I am sorry we are running overtime.

The Subcommittee will stand adjourned.

[Whereupon, at 12:47 p.m., the Subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF ROBERT Cf JOHNSON

"It was 4:30 A.M. when cancer finally choked the last breath of life from Janice Johnson. She was 34, and a mother of two and she died never knowing why her disease had been so unforgiving. An autopsy report called her abrupt decline 'quite unusual'."

"Later, an important clue would be discovered. A hospital laboratory in Arlington, VA., had erroneously reported two successive PAP tests as non-cancerous. Undetected, the cancer spread rapidly through Mrs. Johnson's body."

These were the opening two paragraphs as reported on the front page of the Wall Street Journal, just over a year ago.

I remember that morning as if it were yesterday. In actuality, I was awakened in the middle of the night by the telephone. It was an ever so chilling call from the floor nurse on duty at the hospital. It was not simply that I was told she had died, but that she had regurgitated and choked to death on her own vomit. I was prepared to return to the hospital to pray at her side, but was discouraged by the nurse. She advised that it was a terrible sight and would probably be best if I did not see her in that condition. I acquiesced and did not go, but I might as well have. Every time I think about her untimely demise I have a horrifying picture in my mind of what she probably looked like and it's worse than any nightmare I ever had from Vietnam. This was the end of one year of pain and suffering for Jan, but it was just the beginning of my second year of agony and uncertainty of the future. Our lives would be changed forever and she would never know that her's was a very avoidable and preventable death.

At this point, let me flash back to the beginning of the end, even though we did not know at the time that she was already cancerous, even before she became pregnant, again. The date: August 24, 1979. The event: The birth of our second son, Brandon. Her second pregnancy was extremely uncomfortable compared to the first, but unfortunately we just dismissed it. But then, her post delivery was associated with excessive and abnormal bleeding, severe pains and the frustration of not getting any answers as to why. Nothing seemed to check the bleeding. The gynecological team even inserted an IUD which was removed several weeks later.

Some time in late fall the bleeding finally subsided, although the pain and discomfort was still there. After having missed her cycle for a couple of months, we began to suspect that she was pregnant with a third child, much to our joy. February 1980: We are convinced that she is pregnant, but Jan will go to the GYN-OB, to confirm it. Then, without warning, she developed heavy cramps, sat down, and discharged a large blood clot. The joy quickly changed to fear that she had miscarried. She hastily made an appointment to find out what happened, because now, after all that time, she was bleeding again.

I received a frantic phone call from Jan at my office. She was hysterical . . . crying and talking incoherently. I left the office for home immediately to console her, thinking that she had been told that she had miscarried. Although we had been married for over seven years, I had never seen her in that condition before. The subject of miscarriage never came up. Instead, she completely shocked me when she said that the gynecologists told her that they were able to determine from physical examination that she had cancer. It felt like my entire body had just been imploded. It was the most numbing feeling I ever experienced.

Once it came out that she had been diagnosed as having cervical cancer, I felt relieved. Virtually no one dies from cervical cancer, especially with early detection and treatment. Even though she was aware of the fact that her survival chances were excellent, she was still extremely troubled. She was also reassured by the doctors that she would be just fine after she had a radical hysterectomy, which was performed a couple of days later.

Subsequent to the surgery, Jan and I had several lengthy conversations. The bottom line was, how could this possibly have happened? Cancer doesn't develop overnight and appear during a physical examination! Someone screwed up! We vowed to each other that as soon as she got better, we would investigate and find out who was responsible and shut them down so that this could not happen to anyone else. Unfortunately, Jan would never have the chance.

A year of hell would follow. The deterioration only got worse. . . then week, after week of radiation treatments would be conducted just as a preventative measure to ensure that if any cancer remained, it could be destroyed before being transmitted to the lymph nodes. Later on, this treatment would be followed by chemotherapy, as yet another precautionary measure. One year later, I believe to the day, from the date she was advised of the cancer, her ultimate death was diagnosed as metastatic cancer of the liver. The disease had completely riddled her body.

Janice Johnson was a very extraordinary lady. . . beautiful inside and out . . . well educated and very knowledgeable in the medical field. She was a former educator who came to Washington and joined the staff of a U. S. Congressman. Later, she became the chief lobbyist for one of the large national medical associations. Some of the testimony she authored is in the Congressional Record. She dealt with numerous technical medical issues and even coordinated the association's committee responsible for developing professional standards to ensure proper health care delivery by their physicians. In addition to her medical knowledge, Jan's family had a history of cancer, many of whom died young, and she was very sensitive about this issue. Consequently, she was very cognizant of the warning signs associated with cancer. Yet none of those signs manifested themselves . . . except, in hind sight, the post delivery bleeding.

Yes, the Journal was correct. Janice Johnson died without ever knowing who was responsible for her pre-mature demise. I attempted to carry out the vow that we had made, in Jan's absence, but I failed to succeed. For those involved, who are still living, it's still business as usual!

Yes, Jan was the big loser, because she lost her life, unnecessarily. However, she wasn't the only loser. During the one year that she agonized, she barely knew and had little tolerance toward her two small children . . . pre-occupied by her disease. Sean, who was just 3, and Brandon, not even 6 months old when she took ill, were robbed! They were the children of a mother they would never know. For a solid year, the boys were bounced from house to house. . . from family . . . to neighboring friends to Jan's home nurses . . . and after death, to live-in housekeepers. Even though the children know that Janice was their natural mother, they have absolutely no memory of her at all. During those early days, their maternal bonding was confusing and disoriented.

Exactly seven years and one month ago today we buried my wife. It was a dreadful, blustering, rainy winter day that February. After the funeral, I returned home and sat with my older son. The only thing that Sean can remember is, that day, he and daddy sat down and cried together. It was a most difficult chore to try to explain to him why he would never see his mother again. I used the analogy that the human body protects us like a house in that it protects our soul, and even if that house deteriorates and falls apart, the love and fond memories that live inside will stay with us forever. Mommy's house, or body, got very sick and broken and couldn't protect her soul any longer. Even though you can't see her, she still loves you so much and will watch over you forever.

The only things left that the children will have to remember their mother by are some photographs and a few personal effects which are stored in a small box . . . and a gravesite memorial that bears a poem to their mother. The names of both children are inscribed at the bottom, each adjacent to a rose. . . her favorite flower. The poem reads:

Mother, Woman and Wife,
by cancer early in life,
her grace, love and style
was ours but for a while, -
rode a rainbow to heaven on Feb. 23,

never forgotten by her two boys and me.
Signed. . . her husband.

I wanted everyone who would visit her to know, and for the children to remember, that she did, in fact, die by cancer prematurely, was loved very much, and would be missed by her family.

In my mind, this was not, what has been labelled as, a wrongful death. In my opinion, it is border line criminal. I oftimes ask myself the same questions over and over . . . How many more Janice Johnson's have been unnecessarily killed due to inaccurate lab results during the last 85 months since her death due to either incompetence, fatigue or lack of training? Why is there no self regulation by the medical profession itself, or why not at least some uniform government regulations? How could it possibly have happened? Who was responsible?

Although there was never any admission of guilt by those involved, in my own mind, I believe that all of them, to whatever minor degree, were partially responsible for her death. As I have said before, the laboratory technician may have been the bullet that killed Jan, but there were others who helped hold the gun and pulled the trigger. Who was in charge of overseeing who?

When I was first advised that her PAP smear slides had been misread, I thought it was just an isolated incident. But, I believe that you will discover from additional investigation that this is just the tip of the iceberg. For one to contract and deal with cancer, it is a frightening experience, but to find out that it likely could have been cured if there had been early detection is deplorable.

The question over lab procedures is not a new issue. It has been reviews by the Congress on several occasions. I believe that back in the 1970's, Senators Kennedy and Javitz held hearings on this very issue, but once again, nothing happened because of the pressures of the medical lobby. In fact, my understanding is that little, if anything, has been done since the 1967 Clinical Laboratories Improvement Act. . . and this act covers only a small fraction of the nation's labs who conduct interstate business.

I am sure that future testimony will provide you with a lot of statistics, so let me simply say that we're dealing with big business, that is running rampant and unchecked by any meaningful regulation. I was stunned to learn that it is a 20 billion dollar a year business. I was further shocked by the fact that the cost to review a slide may be as low as $.50. . . yet the bill to the patient can be as high as $35.00. I do not recall what I paid. All I know is that the slide results I got were worthless because they were blatantly misread, in at least two consecutive years that we know of.

If someone had said "It's your money or your wife", I would have gladly paid more for accurate results. Even with all of Jan's medical knowledge, we had no idea of the intricate innerworkings of the system between the doctors and the lab and where the checks and balances are supposed to lie. What protection is the average person getting who doesn't have any knowledge of medicine or how the system works? Frankly, I do not think there is any and that the system is regulated purely by profit motivation.

I understand that the industry standard recommends that 80 slides per day be the maximum number read. I heard that many labs have been found to have read 200 slides per day by a technician. I further understand that in Jan's case the lab technician was reading up to 300 slides per day. I also believe that upon further investigation, it will be revealed that thousands of people who died from cancer did so not because of the disease, but because of the misreading of their slides.

I have used the analogy that when it comes to PAP smears, it is like passing a football - only one thing can go right but several things can go wrong. To name a few: taking an improper specimen; a mix-up in identification; poor chemicals; lost or broken slides; and, of course, untrained, incompetent or overworked lab readers who just did not read the slides properly. Again I ask, where are the checks and balances?

I believe most women will tell you that they absolutely dread the thought of going to their GYN-OB. However, this is where most PAP smears originate. It must be a great feeling of relief when the doctor reports that the slide results were found negative. However, were they really? Most women will probably believe that great news in blind faith. I'll even bet that most people think that their doctor personally rechecks the slides to assure accuracy, and that the patient would be shocked to find out that many of the physicians don't even know how to read a slide.

A builder is only as good as the subs that work for him. Although we thoroughly checked out the GYN-OB team, we made the bad assumption that Jan would be receiving the finest of medical care because they were overseeing the work just like a builder does. An architect who puts his seal on plans does so only after he has reviewed the work of his draftsmen. Where was the head of the lab? How many slides did he review and sign off on, and how many slides did he not review and still sign off on? How many slides did the lab technician read that day? How many slides did other technicians under the same supervision read that day? And. . . perhaps the most important question is, how many slides were misread? How many other people died? How many other people are dieing today and don't even know it? These are but a few of the other questions I ask myself. These are the kind of issues that need to be addressed and questions that need to be answered so that you will be able to more fully comprehend the magnitude of what's really going on.

What happened to my wife was very avoidable! My deep rooted anger is overshadowed only by the pain that I feel over her loss.

There are those who will likely cite rising malpractice insurance costs and suggest that any further regulation woul only serve to further increase rates. I would ask, whatever happened to a stitch in time saves nine? Control the system early on by some uniform system of checks and balances and any potential claims would be averted.

For 21 years now since the passage of Clinical Laboratory Improvement Act, this profession has had the opportunity to regulate itself, and in my judgement, has failed to do so. I usually do not come down the side of additional government regulation, but when an industry fails to respond and the public is at risk, I think it's time to mandate some kind of uniform federal standards to protect the public.

I do not believe that state by state standards will solve the problem because of the "weak link" principle. It will merely produce shoddy labs in states that have weak or no regulations at all. Further, I do not want to imply that the doctors are ignoring the problem or that they are passing the blame on down the line. However, let me cite a recent experience that took place. It reminded me of the Miranda Act, except that it was like the doctor was reading the patient her "rights" and listing disclaimers. The patient went for her annual PAP smear and for the first time ever, was advised, in effect, that the test results are not accurate and went on to read a list of the several things that could go wrong. Is the direction to which we are now headed going to be similar to the consent forms that a patient is required to sign prior to surgery? To me, this is not the solution to the problem. Ensuring accurate test results, to the extent that it is economically feasible, is the solution.

In conclusion, it's been said "everyone is famous for about 15 minutes." I don't know how many other Janice Johnson's there are out there, either dead or dieing because of inaccurate lab results, but hopefully I have spoken on their behalf.

I sincerely hope that Janice and all the other victims who couldn't be here today will feel famous for a lot longer than

15 minutes. I urge that you take decisive, corrective action on this issue and do not succumb, again, to the medical lobby.

Make the right choice. My motivation is merely, if Janice's story can save but one life then I can look my children in the eyes and tell them, when they are old enough to understand, that their mother did not die in vain. She, with the help of Congress, changed the laws to save thousands of lives.

Thank you for your consideration.

Sincerely,

Robert Cf Johnson

Robert Cf Johnson

RCfJ/jw

ASCT
American Society for Cytotechnology

STATEMENT OF

THE AMERICAN SOCIETY FOR CYTOTECHNOLOGY

PRESENTED BY

Patricia R. Ashton

Legislative Consultant

The American Society for Cytotechnology

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT
OF
GOVERNMENT MANAGEMENT

U S SENATE

MARCH 23, 1988

Written Testimony of the
American Society for Cytotechnology
before the
Subcommittee on Oversight of Government Management,
Committee on Governmental Affairs
United States Senate

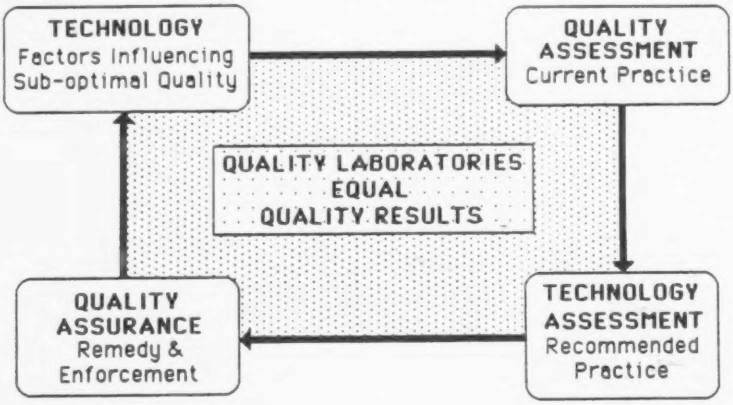
March 23, 1988

Assessment of Current Quality and Federal Regulation of Laboratory Testing, with Special Reference to Cytology Laboratories

Pap smear misdiagnosis poses a major barrier to the decline and elimination of cervical cancer in this country. A valid system of technological assessment of problems in Pap testing, coupled with a strong quality assurance system, would alleviate the barrier of misdiagnosis - a barrier which is currently being scrutinized by the media, government, and laboratory professionals.

The interrelationship of these evaluation systems is demonstrated in Figure 1. **Technology** means factors currently influencing diagnostic quality and accuracy of Pap smears. **Technology assessment** monitors and validates those factors which produce consistently high rates of diagnostic accuracy. **Quality assessment** measures those factors which currently compromise quality. **Quality assurance** monitors and promotes ways to restore, retain, and mandate quality in Pap testing.[1]

Figure 1.


TECHNOLOGY
Factors Influencing
Sub-optimal Quality
QUALITY
ASSESSMENT
Current Practice
QUALITY LABORATORIES
EQUAL
QUALITY RESULTS
TECHNOLOGY
ASSESSMENT
Recommended
Practice
QUALITY
ASSURANCE
Remedy &
Enforcement

The ASCT has applied these definitions to an evaluation of the current status of Pap testing. The following chart summarizes the factors influencing sub-optimal Pap test quality, the recommended practice, the current practice, and the ASCT's recommended remedy. A discussion of each factor follows the chart.

March, 1988

ASCT

TECHNOLOGY Factors Influencing Sub-optimal Quality	TECHNOLOGY ASSESSMENT Recommended Practice	QUALITY ASSESSMENT Current Practice	QUALITY ASSURANCE Remedy
1. Laboratory inspections	Routine lab inspections by qualified Cytotechnologists, using comprehensive guidelines, detect and correct substandard lab operations	Federal inspections are conducted by technologists unfamiliar with cytology practice, using perfunctory guidelines	Require lab inspections conducted by qualified Cytotechnologists; require revision of federal lab. inspection regulations
2. Opportunity to take Pap smears	Any medical contacts with women are opportunities to take Pap smears	Missed opportunities contribute significantly to cervical cancer deaths	Clinician and consumer education would increase Pap testing.
3. Adequate collection of Pap Smear sample	Precancerous lesions of the cervix are detected with greater accuracy when transformation zone is sampled	False negative rates as high as 60% are attributed to poor sampling	Require labs to report inadequate samples; Require labs to monitor clinicians submitting poor samples
4. Pap Test Pricing "Paps for Profit"	Direct-patient-billing eliminates clinician-laboratory kick-back schemes	Labs charge clinicians cut-rate prices; clinicians charge patients full price and pocket profit	Require review of lab billing data by inspectors; Disclosure as required to eliminate kick-backs
5. Technologist Workload	Limit technologist workload to 80 gyn slides/24 hr period (ASCT guideline) to reduce excessive workload that leads to careless errors	Excessive workloads of 200-300 slides per day are reported	Require labs to report technologist caseload and lab volume; Enforce workload guidelines with appropriate sanctions
6. Microscopic Error (Diagnostic Accuracy)	Detection of initial diagnostic errors results in life-saving recall and treatment of the patient	Error rates from 6 - 20% are reported	Require rescreening of all high risk patients; Require documentation of cytotech. and pathologist diagnostic accuracy rates

TECHNOLOGY Factors Influencing Sub-optimal Quality	TECHNOLOGY ASSESSMENT Recommended Practice	QUALITY ASSESSMENT Current Practice	QUALITY ASSURANCE Remedy
7. Diagnostic Reporting	Patient receives proper treatment if diagnoses are properly communicated	Patient mismanagement results from use of ambiguous reporting systems	Require adoption of standardized reporting system
8. Technologist Qualifications	Successful completion of accredited program in cytotechnology and registry exam affirms appropriate knowledge base to detect and interpret abnormal cell changes	Some technologists are practicing with minimum knowledge levels; little to no ability to interpret abnormal cell changes; or, laboratory limits range of diagnoses that could be reported by otherwise qualified cytotechnologist	Require continuing education as condition for individual or laboratory licensure, accreditation, or certification
9. Pathologist Qualifications	A one-year fellowship in cytopathology assures competency to make final cytologic diagnosis	Pathologists are making final cytologic diagnoses with little or no specialty training in cytopathology	Require pathologist training and continuing education in cytopathology
10. Technologist and Pathologist Competency	Proficiency testing detects deficiencies in diagnostic accuracy of cytotechs and pathologists	Only New York State currently operates a proficiency testing program	Require proficiency testing of all technologists and pathologists who practice cytology

Discussion: Assessment of Current Quality of Practice in Cytopathology Laboratories

1. *Laboratory Inspection-The Role of Professional Accrediting Agencies:*
Currently, three professional organizations (the American Society of Cytology, the College of American Pathologists, and the American Society of Clinical Pathologists) have voluntary accreditation programs in cytopathology. The American Society for Cytotechnology has submitted a bid to HCFA to inspect CLIA-licensed laboratories, and hopes to inspect cytology laboratories for HCFA in the near future.

The American Society of Cytology (ASC) conducts a voluntary cytology laboratory accreditation program. In that program, a cytotechnologist and a pathologist are selected by the ASC to inspect a laboratory on-site. Dates and times are pre-arranged with the medical director of the laboratory. The inspection team reviews the application from the laboratory prior to the inspection visit. The inspectors go through a check-list of general requirements for an acceptable operation. The inspectors question the medical director and supervisory cytotechnologist about the daily functions of the laboratory. Upon completion of the inspection, inspectors submit a report to the ASC. Laboratories are accredited by the ASC if they meet the ASC's inspection requirements. Because ASC inspection criteria are general, areas such as microscopic error cannot be sufficiently evaluated.

The College of American Pathologists (CAP) also accredits laboratories. Their inspection criteria are similar to those of the ASC. One frequent difficulty encountered with CAP inspectors is that they are not cyotechnologists or cytopathologists, and consequently are often not familiar with cytology laboratory operations.

The ASCT favors a comprehensive laboratory inspection program which includes verification of cytotechnologist and pathologist workload and diagnostic accuracy. The ASCT has developed an extensive inspection document that details guidelines for scrutiny of every aspect of the laboratory operation. ASCT wants very much to participate in any effort to monitor and maintain quality assurance in cytopathology.

The ASCP Board of Registry administers a national certification examination for eligible cytotechnologist program graduates. They have certified over 9,000 cytotechnologists to date. In August 1988, a bachelor's degree will be required to sit for this examination.

The ASCT favors requiring all cytotechnologists to take this examination. Currently there is no such mandate, nor is there a mechanism for enforcement. Taking this exam will provide additional assurance that practicing cytotechnologists have a sound academic foundation in cytopathology.

The ASCP Board of Registry also offers a Cytotechnologist Specialist Exam. Cytotechnologists who are experienced in the field are eligible to sit for this exam. Management skills in addition to diagnostic cytopathology are tested. The exam was designed to elevate the status of cytotechnologists in the health care field. It is unknown at this time how employers will view this exam in terms of promotion criteria.

2. *Opportunity to Take Pap Smears:* There are a significant number of women who, despite doctor visits and hospitalizations for non-gynecological problems, do not get Pap smears at these times. Studies show that as a result of these "missed opportunities", these women have a higher rate of cervical cancer than women who get Pap smears during non-gynecological medical contact.[12] Carmichael *et al* reported that "of the 245 patients in [their] study, 175 had either unsuitable screening or no screening at all." Morell *et al* said "the 3-year screening interval recommended by the American Cancer Society would appear to decrease the detection of premalignant and malignant disease."[11] Fruchter *et al* reported that 51% of the women in their study "received regular ambulatory care, but at least 27 of these 49 women received no Pap smear as part of this case." Additionally, they noted that "52% of new invasive cancer of the cervix arose in women who had no previous Pap smear."[12]

These statistics are significant. They document the critical need for consumer education programs, as well as programs to remind clinicians to consider any medical contact with women as opportunities to take Pap smears.

March, 1988

3. *Adequate Collection of the Pap Smear Sample:* The main objective of the Pap smear is to detect precancerous lesions of the uterine cervix, which can then be easily treated. These lesions usually occur in the transformation zone of the cervix or in the endocervical canal. Sampling these areas is essential for detecting cervical cancer at its earliest, most treatable stage. However, Husain *et al* reported that 50%-80% of the cases they studied were inadequate.[5] Another study reported "endocervical...cells in only 28% of cases." Carmichael *et al* cite "inadequate or improper sampling of the lesion" as one of the causes of false negatives.[6] The Mayo Clinic attributed 60% of their false negatives to sampling error.[7] These studies clearly show that sampling errors in doctors' offices contribute to high false negative rates for Pap smears.

Frequently clinicians do not properly preserve the cell sample. Poor cell detail compromises diagnostic accuracy. Evans *et al* noted "improvement in the quality of cytological material would increase the consistency of cytodiagnosis".[8] The World Health Organization says "artefacts and preparations that are unsatisfactory for a variety of reasons such as drying and paucity of material are a recurring problem. Since attempts at interpreting such preparations often lead to diagnostic errors, [unsatisfactory Pap smears must be rejected], and a repeat smear requested."[9]

In spite of these sampling problems, many clinicians are offended by such requests and threaten to take their Pap smears to another laboratory. Labs submit to this pressure for fear of losing clinician business. As a result, inadequate smears are diagnosed, even when better judgement would advise against such a practice.

Labs should be required to report inadequate specimens. Records should be maintained in the laboratory which identify clinicians who consistently submit unsatisfactory samples. These clinicians should receive continuing education on proper sampling procedure. Several authors recommend taking two slides per patient decreases sample error.[11] Shulman *et al* reported cancer detection rates increased 86% when two cervical slides were submitted.[10]

4. *Pap Smear Pricing - the "Paps for Profit" Cycle:* Large profit-oriented commercial laboratories advertise Pap smear services for $1.50 or less per case. Clinicians accept these cut-rate prices. However, clinicians continue to charge patients full price (ranging from $15-$35 per patient) and then pocket the profits.[2] As one author pointed out, "the public will easily recognize that for every clinical lab that produces erroneous results, engages in fraud, or overcharges, there is a group of physician patrons who tolerate these conditions through either ignorance, indifference or complicity."

Opportunity for profit is eliminated if patients are billed directly by the laboratory for these services. In fact, Section 1533 of Public Law 93-641 (the National Health Planning and Resources Development Act of 1974) requires "a uniform system for calculating rates that reflect the true cost of providing services to each such category of patients".[3]

Despite these low prices for Pap smear testing, laboratories can still make a profit by manipulating cytotechnologist wages. Cytotechnologists working in these laboratories report such low salaries they are forced to look for additional work to meet living expenses. At the same time, high-volume laboratories need to hire more cytotechnologists to increase production time. Some laboratories offer part-time employment to already full-time cytotechnologists. Other labs tell cytotechs they will pay them by the case (piecework) if they will screen slides above the daily quota. Some labs offer cytotechs cash bonuses for additional slides screened. Cytotechnologists need the money and accept these offers. This practice leads to excessive workloads.

5. *Technologist Workload:* Cytotechnologists, pressured by financial need, succumb to incentives offered by laboratories. They may review 200-300 slides per day, spending approximately 1-2 minutes per slide to microscopically examine thousands of cells for abnormal changes. The risk of missing abnormal changes at that speed are great. The ASCT recommends that no more than 80 (range 70-90) gynecologic slides be examined within a 24 hour period. This allows approximately 5 minutes to examine each slide.[4]

Once an abnormality is detected, the time needed to adequately review a slide can often expand to one hour. Husain *et al* suggested that fatigue and screening too fast cause diagnostic errors. They reported that in their laboratory "6 of 1000 cases containing identifiable neoplastic cells were missed on [initial] screening". They also said "no screener should be pressed to work faster than her[sic] optimum speed."[5]

A large caseload may also require Cytotechnologists to work 12-14 hours per day, often without adequate rest breaks. Husain *et al* have also stated that "it is inadvisable for [cytotechnologists] to spend the whole day at the microscope".[5] Requiring labs to document workloads for each cytotechnologist would help accrediting agencies identify cytotechnologists who are examining huge numbers of Pap smears.

6. *Microscopic Error (Diagnostic Accuracy):* The most significant microscopic error is under-reporting a cellular abnormality present on a Pap smear. The frequency of these interpretive errors varies from lab to lab. Carmichael reported 52 of 299 slides (17.4%) were significantly undercalled in his study.[6] False negative ranges from 6%-55% were reported in other studies, and were caused in part by "incorrect interpretation of the smear."[23] Turner *et al* reported that 6 of 48 patients with invasive cervical cancer in their study had initial Pap smears misinterpreted.[14]

It is critical to the welfare of these patients to detect these errors and alert their clinicians. Strong, effective quality assurance methods are essential to achieve this goal. Methods currently in use include rescreening 10% of negative Pap smears, reinsertion of previously screened cases back into the routine workload, and correlation of diagnoses from patients who have had a Pap smear and tissue biopsy. The success rates of these methods vary, however.

A number of authors believe that 10% rescreening of all negative smears is ineffective and expensive. Rescreening negatives selected by a specific criterion is considered more reliable. Anderson *et al* recommend rescreening a patient's previous negative smears when she first presents with a cytologic abnormality.[15] Greening recommends rescreening all negative Pap smears from high risk patients (history of sexually transmitted diseases, multiple sex partners, multiple births).[16] Husain *et al* said cases "which are suspect because of the clinical history, signs, or symptoms are selected for rescreening in [England]."[5] Several authors recommend that rescreening be assigned to senior or supervisory cytotechnologists because of their expertise and experience.

Data obtained by rescreening can show diagnostic performance rates for each cytotechnologist and pathologist in a laboratory. These data should be examined monthly by the medical director and supervisory cytotechnologists. Cases that are undercalled or overcalled should be reviewed with the cytotechnologist or pathologist who made the error to determine the reason for the misinterpretation. Continued review of study cases similar to the ones misdiagnosed will correct deficiencies in cell criteria.

Anderson *et al* documented the undercall, overcall, and false negative rate for each cytotechnologist in their laboratory. Review of these cases resulted in undercalls declining from 269 to 138 in one year.[15]

Further information on diagnostic accuracy can be obtained by reviewing biopsy diagnoses on patients who have had abnormal Pap smears. If the cytologic diagnosis and histologic diagnosis differs significantly, the laboratory director and supervisory cytotechnologist should determine the reason. If Pap smears are consistently overcalled or undercalled, a continuing education program in cell diagnosis can be implemented to correct these errors.

In laboratories where both Pap smears and biopsies are received, all Pap smears from women who have had biopsies should be reviewed and correlated with the biopsy. Of course the latter method is more difficult when 3000 miles separate the Pap test lab and the biopsy lab. Concurrent examination of cytotechnologist workload figures will determine if the misdiagnosis is due to reviewing too many slides.

7. *Diagnostic Reporting Systems:* Laboratories and clinicians are communicating patient diagnoses using at least six widely variable reporting systems. The risk of misunderstanding is great, and the consequence for the patient if such an error occurs is even greater - she may receive unnecessary treatment or no treatment at all. For example, in Lab A, a "Class IV" designates invasive cervical cancer, meaning the patient is a candidate for a hysterectomy or radiation therapy. But in Lab B, a "Class IV" designates a severe precancerous process, meaning the patient can be spared extensive surgery and radiotherapy, simply having the affected tissue removed. If a clinician now sending specimens to Lab A decides to send his specimens to Lab B, he may assume Class IV in the new lab means the same as it did in the previous lab, and will treat his patients accordingly.

The optimal method of reporting diagnoses is to describe the condition in histopathologic terminology. Cytotechs told ASCT in a quality control survey that even though they prefer this descriptive system, they still use the ambiguous Class system because clinicians prefer it.[13] Some clinicians will even go as far as threatening to take their business elsewhere if the laboratory does not use the reporting system they prefer. Laboratories may acquiesce to this pressure simply to retain the clinician's account.

Laboratories and clinicians should be required to adopt a uniform descriptive reporting system, thereby eliminating the hazard for improper patient treatment.

8. *Technologist Qualifications:* Cytotechnologists are not only responsible for detecting abnormal cell changes. They must be able to interpret what those changes mean. These decisions mandate a rigorous, minimum 12-month training program as an absolute essential for cytotechnologists. It is also advisable that cytotechnologists take and pass a certification examination. In August, 1988, a bachelor's degree will be required to sit for the ASCP's Cytotechnologist Certification Examination. Cytotechs have told ASCT there are technologists practicing who are only able to recognize abnormal cell changes

and are not capable of interpreting what disease process those cells represent. There are other cytotechnologists practicing who have been unable to pass a certification examination.

A sound, comprehensive knowledge base in cell morphology and pathology, coupled with continuing education, can improve the technologist's diagnostic ability significantly. Chang *et al* said the Pap smear is a successful screening method for cervical cancer if two conditions are met: first, "the specimen must be adequate; and second, the Pap smear must be evaluated by a competent cytologist."[21] Snyder *et al*, when discussing the difficulty sometimes encountered in distinguishing severe precancerous lesions from invasive cancer, indicated they considered "the skill of the observer to be important in the interpretation."[24] Husain *et al* pointed out that in laboratories where the majority of Pap smears are negative, the cytotechnologist reports most of the diagnoses.[5] These authors noted the responsibility this places on the cytotechnologist. They futher say "[the cytotechnologist] must be fully aware of all the features which make a smear 'unsatisfactory' or, what is more difficult, to be able to recognize a suboptimal sample."[5]

Currently the number of practicing, qualified cytotechnologists is declining. Cytotechs leaving the field tell ASCT they can no longer tolerate the low salaries and can find more financially attractive positions elsewhere.

9. *Pathologist Qualifications:* Consider the following scenario: A cytotechnologist has detected abnormal cells on a Pap smear. She makes a preliminary diagnosis and forwards the case to a pathologist for final interpretation. He makes a diagnosis of cervical cancer. The patient is now a candidate for surgery or radiotherapy .... It should be of great concern to this patient that, amidst all the other factors influencing the accuracy of her Pap smear, this pathologist has very little training in cytopathology. Husain *et al* say that "to maintain reasonable uniformity of quality of cytology reports throughout the country, proper training of cytopathologists is of first importance...".[5]

Many pathologists have little or no training in cytopathology. Others have completed a three month rotation through a cytology laboratory. Still others have completed a one-year fellowship in cytopathology. Pathologist training concentrates on diagnosing disease by microscopic examination of tissues. The morphologic appearance of tissue versus cells or groups of cells removed from tissue, i.e, taken "out of context", is dramatically different. Pathologists with limited training in cytopathology tend to render non-specific diagnoses such as "suspicious" or " cancer not ruled out." Clinicians cannot plan treatment based on such sketchy feed-back and consequently the patient undergoes additional testing. This defeats the very purpose of a cytologic diagnosis - to detect the disease process and provide an interpretation specific enough to allow the clinician to proceed to the next major step in patient management.

Many of these pathologists, while recognizing their lack of training in cytopathology, do not attempt to improve their diagnostic ability by participating in a comprehensive continuing education program. It is for this reason that pathologists, as well as cytotechnologists, be included in proficiency testing and mandatory continuing education programs.

10. *Measuring Technologist and Pathologist Competency:* A method that must be used to safeguard against significant microscopic error rates is mandatory

proficiency testing for every practicing cytotechnologist and pathologist. In most proficiency testing programs, cytotechnologists and pathologists are given test slides to examine and diagnose. Abnormal test slides have histologically proven diagnoses. Results are graded and any diagnostic errors are noted. Continuing education is recommended to correct errors and individuals are the retested. A state or federal agency could go as far as stopping the practice of cytopathology in that laboratory if personnel cannot pass a proficiency test.

New York state has administered 3,368 proficiency tests to cytotechnolologists and pathologists over a 14 year period. Data from this program show a steady increase in test "pass-rates" and a decline in retests. More specifically, "the proportion of successful first tests has risen from 73% in 1972-1973 to 90.5% in 1982-1984." The study concludes that "periodic inspection and testing of laboratories, withholding of permits from substandard facilities, and especially a comprehensive program of continuing education, have contributed to this improvement in laboratory performance and the maintenance of a high level of competence."[17]

The proficiency testing program in Ontario, Canada showed that test results pinpointed specific areas where continuing education was needed. Program officials developed and distributed educational programs for these special problems. They said that testing enabled them to meet their goal of identifying "laboratories that perform at lower levels of proficiency." Moreover, they can monitor laboratory improvement with educational programs and retesting.[18]

Authors also note some disadvantages to proficiency testing. First, wide variations in diagnostic reporting systems present difficulties in grading test results. Adoption of a uniform reporting system would alleviate this problem.

Second, glass test slides will eventually fade due to age, and slides may be broken in transit. Several authors (Greening, Rube) and professional societies (ASCT, ASCP) have recommended proficiency testing using videodisc technology. Test slides can be videotaped to simulate actual microscopic examination. Patient information can also be pressed to disc. Examinees viewing this "screening simulation" can stop the movement of the cells, make an analysis, and enter results. A computer can record all responses for scoring. Computer programs can branch to allow the examinee to search clinical history.

Such a program eliminates the concern for faded or broken slides. Patient material does not have to be removed from the laboratory. Validity of results is enhanced because participants nation-wide see the same cells. Most laboratories are either computerized or are becoming computerized, meaning the equipment necessary for testing is already present in the laboratory. The initial investment for developing a videodisc and computer program is admittedly costly - $100,000 to $250,000. However, copies of the videodisc for distribution to test sites are only $20-$25 each. Federal or state testing agencies can communicate with test sites via modems to obtain test results. The need and expense of on-site administration of the test is eliminated. As the success of videodisc systems in health care education has already been proven, this methodology can also be used for phase two of the proficiency testing process - continuing education to correct diagnostic deficiencies.

The most important justification for strong quality control programs is that a significant number of invasive cervical cancers are now appearing within a few months to a year after women have had negative Pap smears. Bain *et al* estimate the "[25-30%] of patients have rapid development of cervical cancer".[19] In many cases, review of previous Pap smears from these women revealed no significant abnormality. Carmichael *et al* call attention to Berkleley's study where "all the women with cytologic abnormalities (regardless of how minor) [developed] invasive cervical cancer within 5 years."[6]

Chang *et al* reported a "dramatic rise in abnormal smears" - 91 cases from 1973-77, as compared to 291 cases from 1978-82.[21] In England, researchers report a "threefold rise in cervical cancer mortality...since 1965".[22] In view of these studies, Carmicheal *et al* emphasize the "need to repeat smears within 2-3 months for women who have atypias or mild dysplasias." [6]

The most frightening aspect of this phenomenon is its occurrence in young women. Precancerous lesions [dysplasia or cervical intraepithelial neoplasia (CIN)] are increasing in women age 25 and younger. Invasive cancers are being detected in women age 25-35. A South Carolina gynecologist notes "a 2.5% incidence of dysplasia or worse in women under 20."[22]

Several researchers have proposed theories of "two populations of cervical carcinoma" - one taking up to 20 years to become invasive; the other taking only a few months."[23] Other authors equate the rise in precancerous lesions and rapid transition to cervical cancer with the concurrent rise in Human Papilloma Virus (HPV) infections. A South Carolina gynecologist says all of her patients with dysplasia also have HPV. Goldstein from Children's Hospital in Boston says that "at least 5% of cervical smears taken at [his institution] have evidence of papilloma-virus infection".[22] Other reports say "HPV positive women were nearly six times more likely than those not infected to have an abnormal Pap smear...."[22]

Current theories propose that certain strains of HPV accelerate the transition to invasive cervical cancer. Researchers at the German Cancer Institute in Heidelberg, West Germany have identified HPV in cervical cancer cells in a significant number of cases.[22]

Laboratories cannot afford to make diagnostic errors on Pap smears from these patients. Laboratories and clinicians once enjoyed the luxury of knowing if abnormal cells were missed on a patient's Pap smear, they would most likely be detected the following year with no detriment to the patient. This is no longer true. Missed cells from a rapid-transition lesion now place the patient's life in grave jeopardy.

Detection of microscopic errors requires a "package" of quality control methods. No one method is self-reliant. The ASCT recommends:
(a) rescreening of negative smears on all high risk patients
(b) cytologic-histologic correlation studies, and
(c) mandatory proficiency testing.[16]

March, 1988

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SUMMARY: The ASCT, speaking for the profession of cytotechnology, recommends immediate regulatory action by both legislative and professional bodies.

Development, implementation, and enforcement of the following quality assurance methods will be instrumental in achieving quality in the cytology laboratory - quality that patients should expect and to which they have a right:

1. Mandatory proficiency testing of cytotechnologists and pathologists
2. Workload guidelines, based on the ASCT recommendations
3. Direct patient billing
4. Retrospective rescreening of negative Pap smears from high risk patients, coupled with histological and/or clinical correlation studies
5. Mandatory continuing education
6. Required formal education for cytotechnologists and pathologists
7. Laboratory inspection conducted by trained, professionally experienced cytotechnologists
8. Required documentation of cytotechnologist workload, cytotechnologist and pathologist diagnostic accuracy, and clinician sampling performance

The ASCT is prepared to work with legislators and other professional organizations to activate this quality assurance program as soon as possible.

This document was prepared for the ASCT by Carol M. Trew, current ASCT President, and Shirley E. Greening, ASCT Past-President. 3/18/88

March, 1988

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Testimony of George Hoffman, M.D.
Before
the Senate Governmental Affairs Subcommittee
on Oversight of Government Management

March 23, 1988

Mr. Chairman, I'm George Hoffman M.D, a physician Board-certified in pathology and President of the American Society of Clinical Pathologists (ASCP), an educational and scientific organization with over 40,000 pathologists, other physicians, clinical scientists, certified technologists and technicians. I practice at the Cleveland Clinic Foundation, a not-for profit group practice of over 500 salaried physicians in Cleveland, Ohio. Until recently I was Director of Laboratories. With me today is Catherine Cohen, Director of the ASCP Washington Office.

We welcome to opportunity to comment on the quality of clinical laboratory testing, and to make recommendations. We are concerned that recent media reports on the quality of clinical laboratory testing have spurred a "crisis of confidence" in the current regulatory system and in the clinical laboratory. Laboratories approved today, whether under Medicare, through the Clinical Laboratory Improvement Act (CLIA), or by the College of American Pathologists (CAP) generally produce testing of high quality.

High "quality" in testing is best defined as the provision of appropriate, clinically relevant information as needed for good patient care.[1] This involves much more than accuracy of test results. Other benchmarks are appropriate test selection, proper specimen handling and correct interpretation of results. We believe that quality of testing in unregulated settings has not been fully evaluated, and steps should be taken to assure quality testing in these as in all settings.

Critical to high quality health care is the assurance that individuals performing laboratory tests are able to carry out their responsibilities effectively with an understanding of the many factors which affect the quality of that testing. The ASCP is committed to the view that laboratory personnel of demonstrated competency are of prime importance in quality assurance.

There is a real concern in some areas of testing, however, about serious financial disincentives to produce a quality product. Reimbursement must be adequate to permit laboratories to provide quality testing. Cytology testing, particularly Pap smear testing, is an example of a situation in which problems can arise from such financial pressures. As payment for laboratory testing in general is tightened, cytology's problems can be expected to occur in other areas of testing.

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[1] Quality Testing includes: 1) appropriate test selection; 2) prevalence of the disease in question in the population tested; 3) preparation of patient; 4) conditions of phlebotomy; 5) specimen handling separation and storage; 6) analytic precision and accuracy; 7) the reference range reported with the test result; and 8) timeliness of the result.

As my colleague has mentioned, financial pressures on laboratories have spurred some unprofessional practices in efforts to screen too many Pap smear slides during a given time period. While amounts paid by patients and third party payers for Pap smear testing generally are adequate, most of these payments are made to the ordering physician, not the laboratory. A significant percentage of the money paid for Pap smears, therefore, is not directed to its intended purpose, i.e., to pay for the review of the smear. Payments ultimately made to laboratories for Pap smear testing are insufficient to support the quality of screening the experts have set as standard. Laboratories which offer a variety of services including high quality cytology, will tell you that cytology is a money loser. That is, the laboratory frequently takes a loss on Pap smear testing in order to compete with pricing offered by cytology-only operations and to obtain other clinical laboratory testing business from the physicians.

One way of achieving the adequate payment to laboratories without substantially increasing costs to patients and third-party payers is to increase the number of Pap smears billed directly by the laboratory. Medicare, as you know, has a direct billing requirement. States could impose direct billing requirements similar to Medicare's. The Federal government could use the "Commerce Clause" as with CLIA, to impose direct billing requirements on non Medicare lab testing.

On the question of personnel, quality in the laboratory cannot be achieved without quality laboratory personnel. The laboratory director has a critical role in determining laboratory quality through setting standards for quality control and personnel as well as on going determination of clinical relevance of data. The pathologist is the most qualified for this broad responsibility. (Competency characteristics, listed in full statement) In addition to the pathologist or other physician directing the laboratory, there are many nonphysician professionals who work in the laboratory. These individuals, primarily medical technologists, are responsible for performing most of the tests. Subspecialties within medical technology include clinical chemistry, hematology, blood banking and immunology. Related specialties include histotechnology and cytotechnology.

The ASCP Board of Registry, established in 1928, is the oldest and largest certification agency for clinical laboratory personnel having certified over 278,000 individuals. To date, ASCP has certified 175,000 Medical Technologists, 14,400 Histologic Technicians, 9,000 Cytotechnologists, 16,200 Categorical MTs and Specialists and 60,000 Technicians (CLA, MLT). The ASCP Board of Registry's Board of Governors includes representatives of the American Academy of Microbiology, the American Association of Blood Banks, the American Society of Cytology, the National Registry in Clinical Chemistry, the American Society of Hematology, and the National Society for Histotechnology.

The ASCP Medical Technologist certification, with its prerequisite of a baccalaureate degree, is a widely sought label of quality by many laboratories when hiring personnel. Medicare and CLIA regulations, while not requiring laboratories to hire ASCP certified individuals, recognize the baccalaureate degree as one of the methods of qualifying as medical technologists. These Federal personnel standards, however, may be reduced substantially in a HCFA laboratory regulation reform expected to be published in the Federal Register this April. The potential for increased inaccuracies in testing as a result of such a move is of great concern to ASCP. This HCFA move to reduce personnel standards appears to conflict with other efforts in the Department of Health and Human Services to strengthen laboratory personnel standards (e.g., National Institute of Drug Abuse (NIDA) proposed standards for drug testing laboratories).

There has been much discussion on the need for a minimum level of education to accurately perform the duties of a medical technologist. The American Society of Clinical Pathologists contends that education is essential to ensure quality of care. Requirements that an individual complete a prescribed set of courses, particularly in the sciences, combined with clinical education and experience ensures that individuals have adequate knowledge and experience to perform in the laboratory.

The impact of certification, standardized education and clinical experience in laboratory performance, has been empirically demonstrated by a study of medical technologists employed in laboratories licensed by the state of Illinois. The results of that study, published in the July 17, 1987, edition of the Journal of the American Medical Association (JAMA), found a significant positive correlation between certification and performance on College of American Pathologists (CAP) proficiency surveys. The CAP's proficiency survey program is a widely respected education tool and is recognized as meeting CLIA and Medicare requirements. In evaluating the performance of those laboratories, the study found that labs employing all certified medical technologists produced significantly more accurate results on CAP PT than did labs employing only noncertified medical technologists. In laboratories employing both certified and noncertified laboratory personnel, the study found that "the higher the proportion of certified technologists, the higher the accuracy on CAP surveys."

The impact of the lack of educational requirements for laboratory personnel on laboratory accuracy is especially evident in the case of physician office laboratories. A study by Richard Belsey, M.D., et al., also printed in the July 17, 1987, JAMA, evaluated lab instruments which were used in physician offices hospitals and independent laboratories. This study found an increased variability in test results when performed by personnel representative of those generally found in the physician's office lab. While physicians are ultimately responsible for the quality of the testing in their laboratory, the potential for mistakes in diagnostic screening due to inadequately trained personnel is overwhelming.

In the past, there has not been a problem finding adequately trained nonphysician laboratory professionals to work in the laboratory. Now, however, there are fewer students entering the field of medical technology. This is due in part to economic pressures on hospitals--the location of most medical technologist schools--and the concern about occupational exposure to AIDS.

Over 25% of schools of medical technology have closed since 1982. Cytotechnology schools have been among hardest hit, with over 40% closed since 1980. Since the majority of these schools are hospital-based rather than university-based, this disturbing trend can be expected to continue as long as Federal reimbursement to hospitals is reduced. ASCP asks for your support for a number of other mechanisms we are proposing to improve the allocation of Federal money to these schools. Specifically, we recommend that Federal grant opportunities under Title VII Health Professions Education Reauthorization be made available to all allied health schools to develop programs to attract qualified students. Title VII presently only provides grant opportunities for recruitment of disadvantages students.

Let me end by emphasizing our major: the gaps in regulation of laboratory testing need to be closed, financial pressures on cytology must be and Federal standards for laboratory personnel must be preserved.

STATEMENT OF
THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
to the
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
RE: THE QUALITY OF CLINICAL LABORATORY TESTING
MARCH 23, 1988

Overview

The American Society of Clinical Pathologists (ASCP) appreciates this opportunity to comment on the status of clinical laboratory testing available to Medicare beneficiaries and to make recommendations for improving the quality of such testing. We are concerned that recent press reports on the quality of clinical laboratory testing have spurred a "crisis in confidence" in the current regulatory system and in the clinical laboratory. Laboratories approved today, whether under Medicare, through the Clinical Laboratory Improvement Act (CLIA) or by the College of American Pathologists (CAP) generally produce testing of high quality. The beneficial affect of such review on the quality of laboratory testing has been amply demonstrated.

High "quality" in testing is best defined as the provision of appropriate, clinically relevant information as needed for good patient care.[1] We believe that quality of testing in unregulated settings has not been well evaluated, and steps should be taken to assure quality testing in these settings.

Critical to high quality health care is the assurance that individuals performing laboratory tests are able to carry out their responsibilities effectively with an understanding of the many factors which affect the quality of that testing. The ASCP is committed to the view that laboratory personnel of demonstrated competency are of prime importance in quality assurance.

There is a real concern in some areas of testing, however, about serious financial disincentives to produce a quality product. Reimbursement must be adequate to permit laboratories to provide quality testing. Cytology testing is an example of a situation in which problems can arise from such financial pressures. A report prepared for the National Committee for Quality Health Care by Dr. Robert Rubin of Lewin/ICF, found that the health care available to us in the future depends on the payment systems in place and their incentives. As payment for laboratory testing in general is tightened, these problems can be expected to occur in other areas of testing.

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[1] Quality Testing includes: 1) appropriate test selection; 2) prevalence of the disease in question in the population tested; 3) preparation of patient; 4) conditions of phlebotomy; 5) specimen handling, separation and storage; 6) analytic precision and accuracy; 7) the reference range reported with the test result; and 8) timeliness of the result.

The ASCP is a nonprofit medical specialty society organized for educational and scientific purposes. Its membership numbers over 40,000 board-certified pathologists, other physicians, clinical scientists and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers over 140,000 certified laboratory professionals annually.

Adequacy of Current Regulatory Structure

The current regulatory structure under Medicare and CLIA has had a significant positive impact on the quality of laboratory testing. Some aspects of these programs, however, could be modified to further improve laboratory performance. Under the Medicare program, the Health Care Financing Administration (HCFA) contracts with state agencies to conduct surveys and inspections of hospital and independent laboratories. Although attempts are made by HCFA and the Centers for Disease Control (CDC) to train surveyors and standardize such inspections, the quality of the review varies greatly.

Medicare could benefit from expanding the options available for survey and accreditation. Of particular benefit, in our view, would be increased use of private agencies with proven track records and with quality reputations such as the College of American Pathologists (CAP), which has had equivalency with CLIA licensure program since 1967. CAP applied for "deemed status" for Medicare in August of 1984 and still awaits a decision by HCFA. HCFA has been hesitant to provide "deem status" to any private agency for laboratory inspections despite the fact that the authority has existed since 1984 and Congress intended that the Medicare program should benefit from that private sector option. On site inspections by competent persons are an essential component of efforts to assure quality.

Another regulatory improvement would be a standardized laboratory evaluation system. Currently, laboratories are required to subscribe to one of a number of proficiency testing (PT) programs acceptable to the Secretary. These programs are an important part of the Federal and State lab evaluation system. They vary, however, in degree of challenge. The concept of a uniform PT program recently initiated by CDC is on the right track for improving this situation. A uniform evaluation system would go a long way toward improving HCFA's ability to identify problems in the clinical laboratory. Because PT has always been a laboratory educational tool, we are concerned about immediate use of such a new program for regulatory purposes. We recommend a phased-in transformation, recognizing existing programs.

Two major areas are identified for improved federal control: Pap smear and unregulated testing. A discussion of the problems and recommendations for these areas follows:

Pap Smears

While reports of false negative rates have, in our opinion, been overstated, ASCP is concerned about unprofessional practices in efforts to screen too many Pap smear slides during a given time period. Experts and professional associations have issued recommendations on the appropriate number of slides or case load reviewed per technologist based on time needed to thoroughly evaluate the smear. While the technologist's abilities will vary, there are numbers of slides being reviewed in some laboratories which most professionals would agree threaten the quality of review. The underlying reason for this situation in some cytology laboratories is the serious economic disincentives to produce a high quality product.

While amounts paid by patients and third party payers for Pap smear testing generally are adequate, most of these payments are made to the ordering physician, not the laboratory. A significant percentage of the money paid for Pap smears, therefore, is not directed to its intended purpose, i.e., to pay for the review of the smear. Payments ultimately made to laboratories for Pap smear testing are insufficient to support the quality of screening the experts have set as standard. Laboratories which offer a variety of services including high quality cytology, will tell you that cytology is a money loser. That is, the laboratory frequently takes a loss on Pap smear testing in order to compete with pricing offered by cytology-only operations and to obtain other clinical laboratory testing business from physicians.

Obviously, laboratories which offer only Pap smear testing must conduct business differently in order to make a profit and thereby survive financially. When this testing is offered for as low as $2-$4 per case, something has to suffer. Those laboratories which are regulated under Medicare must meet standards for quality control (10% re-review), personnel qualifications, and recordkeeping. The major cost saving technique in these settings, therefore, is increasing the number of slides reviewed per cytotechnologist. Technologists are sometimes paid on piecework basis at rates so low that an unsafe number of slides would have to be reviewed in order to make a living wage.

Medicare has had a direct billing requirement for clinical laboratory testing, including Pap smears, since 1984. This requirement gives physicians the incentive to perform Pap smear evaluations in their offices, and HCFA data seems to suggest that this is occurring. This phenomenon raises concerns about the lack of Medicare inspection and standards in that setting. Clinical laboratories may not identify Medicare cases which need to be billed directly. Laboratories do not automatically have access to insurance and other information about patients whose Pap smears they are reviewing. The patient's physician must identify Medicare beneficiaries in order that the laboratory may directly bill Medicare for the service.

The ASCP makes the following recommendations to improve the performance of Pap smear review. Without changing the adverse economic incentives, however, these requirements would be difficult to implement.

1. Screening of a cervical/vaginal (Pap) smear should be performed in an accredited laboratory by certified cytotechnologists;

2. Reasonable limitations on the daily volume of cytological smears examined and the number of hours worked by each cytotechnologist should be based on recommendations of professional organizations;

3. Cytology screening should be performed under the supervision of a cytopathologist or certified pathologist who has appropriate experience in this field;

4. The pathologist who directs the cytopathology laboratory should establish and administer an on-going quality assurance program with standards recognized by national professional organizations;

5. An extra-institutional proficiency evaluation tool should be developed to aid implementation of a quality assurance program.

Quality assurance programs should be outcome oriented and include all aspects of laboratory operation. Continuing education and periodic proficiency evaluation of personnel are important parts of overall quality assurance. These evaluation tools should be tied to educational opportunities for participants.

The ASCP believes that Pap smear tests should be available to all patients at a reasonable cost. Laboratories must be paid adequately to meet the above standards for a quality product. One way of achieving the adequate payment to laboratories without substantially increasing costs to patients and third-party payers is to increase the number of Pap smears billed directly by the laboratory. States could impose direct billing requirements similar to Medicare's. The Federal government could use the "Commerce Clause" as with CLIA, to impose direct billing requirements on non Medicare laboratory testing.

Unregulated Testing

Growing numbers of clinical laboratory tests today are performed in settings which are not regulated by Medicare, CLIA, or state programs. At least 25 percent of all outpatient testing is performed in physicians' office laboratories. Medicare now pays for more outpatient testing in physicians' office laboratories than in independent laboratories. This shift in site of testing to unregulated settings raises serious questions about quality. Medicare does not currently impose health and safety standards on physicians performing testing in their offices on their own patients. Congress has expressed concern about the amount and quality of testing performed in physicians' office labs (POLs) and asked HCFA to recommend health and safety standards appropriate for that setting. When HCFA did not respond to the mandate, Congress included a provision in the Omnibus Budget Reconciliation Act of 1987 to impose the same standards on high volume POLs beginning in 1990 as those required for independent laboratories.

Congress attempted to get at the question of standard quality testing for beneficiaries by targeting POLs conducting substantial amounts of clinical laboratory testing similar in scope to that of hospital and independent laboratories (over 5000 tests per year). It is important to note, however that POLs conducting a low volume of tests were exempt. To a certain degree, laboratory performance improves as volume increases and therefore we continue to have concerns about this setting. We are encouraged by the voluntary efforts to develop assessment or accreditation programs for physician office laboratory settings. The Commission on Office Laboratory Assessment (COLA), a voluntary educational and assessment program for physicians office laboratories, could be ready within a year to provide this service as an independent private sector agency. COLA is under development by the CAP, the American Society of Internal Medicine (ASIM), and the American Academy of Family Physicians (AAFP).

There are other settings where testing is not required to meet any standards. Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) and other long term care facilities were recently targeted by HCFA for imposition of laboratory standards similar to those of hospital and independent laboratories because of reports of substantial clinical laboratory testing performed in these settings. These proposals, however, have not been finalized. The General Accounting Office recently reported that as many as 13 states did not regulate independent laboratories and several did not even license hospital labs. Laboratories in those states which choose not to perform work for Medicare or engage in interstate commerce could escape any requirements or standards.

The Role of Personnel

Quality in the laboratory cannot be achieved without quality laboratory personnel. The laboratory director has a critical role in determining laboratory quality through setting standards for quality control and personnel as well as on going determination of clinical relevance of data. The pathologist is the most qualified for this broad responsibility (See competency characteristics, Attachment I).

In addition to the pathologist or other physician directing the laboratory, there are many nonphysician professionals who work in the laboratory. These individuals, primarily medical technologists, are responsible for performing and screening most of the tests. Subspecialties within medical technology include clinical chemistry, hematology, bloodbanking and immunology. Related specialties include histotechnology and cytotechnology.

The ASCP Board of Registry, established in 1928, is the oldest and largest certification agency for clinical laboratory personnel, having certified over 278,000 individuals. ASCP offers certification examinations as follows:

Medical Laboratory Technician, MLT(ASCP)

Medical Technologist, MT(ASCP),

Categorical Technologists	
(in Blood Banking	BB(ASCP)
Chemistry	C(ASCP)
Hematology	H(ASCP)
Histotechnology	HLT(ASCP)
Immunology	I(ASCP)
Microbiology)	M(ASCP)
Histologic Technician	HT(ASCP)
Cytotechnologist	CT(ASCP)

Specialist
(SBB, SC, SH, SI, SM, SCT, all of the categories listed above except histoechnology)

The requirements to sit for these certification examinations are spelled out in attachment II.

To date, ASCP has certified 175,000 Medical Technologists, 14,400 Histologic Technicians, 9,000 Cytotechnologists, 16,200 Categorical MTs and Specialists and 60,000 Technicians (CLA, MLT). The

ASCP Board of Registry's Board of Governors includes representatives of the American Academy of Microbiology, the American Association of Blood Banks, the American Society of Cytology, the National Registry in Clinical Chemistry, the American Society of Hematology, and the National Society for Histotechnology.

The ASCP Board of Registry has strict educational prerequisites for individuals seeking to sit for an ASCP certifying examination. Medical Technologist applicants must be graduates of an approved program which includes 16 semester hours of chemistry, including one course in organic biochemistry, and 16 hours of biological science, including one course in microbiology and course work in immunology. Cytotechnologists must have 20 hours of biological science and 8 hours in chemistry. Effective August 1988, individuals wishing to sit for ASCP's cytotechnology examination must have a baccalaureate degree.

ASCP Medical Technologist certification, with its prerequisite of a baccalaureate degree, is a widely sought label of quality by many laboratories when hiring laboratory personnel. Medicare and CLIA regulations, while not requiring laboratories to hire ASCP certified individuals, recognize the baccalaureate degree as one of the methods of qualifying as medical technologists. These Federal personnel standards, however, may be reduced substantially in a HCFA laboratory regulation reform expected to be published in the Federal Register this April. The potential for increased inaccuracies in testing as a result of such a move is disturbing. This HCFA move to reduce personnel standards appears to conflict with other efforts in the Department of Health and Human Services to strengthen laboratory personnel standards (i.e., for drug testing laboratories).

There has been much discussion on the need for a minimum level of education to accurately perform the job. The American Society of Clinical Pathologists contends that education is essential to ensure quality of care. Requirements that an individual complete a prescribed set of courses, particularly in the sciences, combined with clinical education and experience ensures that individuals have adequate baseline knowledge and experience to perform in the laboratory.

The impact of certification, standardized education and clinical experience in laboratory performance, has been empirically demonstrated by a study of medical technologists employed in laboratories licensed by the state of Illinois. The results of that study, published in the July 17, 1987, edition of the Journal of the American Medical Association (JAMA), found a significant positive correlation between certification and performance on College of American Pathologists (CAP) proficiency surveys. As mentioned earlier, the CAP's proficiency survey program is a widely respected education tool and is recognized as meeting CLIA and Medicare requirements. In evaluating the performance of those laboratories which do not employ certified individuals, the study found "unacceptable results on CAP surveys approximately one in four times." In laboratories employing both certified and noncertified laboratory personnel, the study found that "the higher the proportion of certified technologists, the higher the accuracy on CAP surveys."

The impact of the lack of educational requirements for laboratory personnel on laboratory accuracy is especially evident in the case of POLs. A study by Richard Belsey, M.D., et al., also printed in the July 17, 1987, JAMA, evaluated testing systems which were used in physician office laboratories, hospitals and independent laboratories. This study found an increased variability in test results when performed by personnel representative of those found in the POL--i.e., physicians, nurses, clerks. While physicians are ultimately responsible for the quality of the testing in their laboratory, the potential for mistakes in diagnostic screening due to inadequately trained personnel is overwhelming.

In the past, there has not been a problem finding adequately trained nonphysician laboratory professionals to work in the laboratory. Now, however, there are fewer students entering the field of medical technology. This is due in part to economic pressures on hospitals--the location of most medical technologist schools--and the concern about occupational exposure to AIDS.

There are a number of other reasons, however, for this situation including a declining number of high school graduates. In general, allied health care has a perceived negative image by the public accompanied by feelings of a "lowered status" among health care providers. Additionally, medical technology has traditionally been a female-dominated profession. A wide variety of employment opportunities exist for women today.

The problems resulting from all of these changes are somewhat circular: fewer students are entering the field, schools which do not have enough students are closing, students choosing to enter the field are having increasing difficulties finding schools that are open.

The trend for closures of schools of medical technology is a significant problem considering the need for appropriately trained medical technologists. Over 25% of the medical technology programs have closed since 1982. Of the 694 programs open in 1982, only 504 programs remain.

A substantial number of all medical technology training programs is hospital-based. This means that the hospital is the accredited site for the clinical education. Hospital-based programs face particular financial problems, primarily as a result of the Prospective Payment System (PPS). There is no doubt that the PPS has forced hospitals to become more cost conscious. When hospitals are forced to "tighten their belts" as a result of lower reimbursement for patient care, cuts are made in areas such as allied health educational programs which do not contribute directly to patient care and traditionally cost the hospital money to run. Thus, the cycle continues, less funding, fewer schools, fewer students, fewer qualified individuals to work in the laboratory. Cytotechnology schools have been among the hardest hit with over 40 percent closed since 1980. Only 40 programs are active today.

Assistance is needed to break this vicious cycle and improve the supply of quality laboratory personnel. While ASCP has engaged in activities to recruit qualified students into the field and to assist program development, help from the federal government is imperative. The funds received by hospital-based programs as a direct pass-through in the Medicare program, are insufficient to prevent future school closings. Futhermore, university-based programs do not receive any funds through Medicare. The reauthorization of Title VII of the Public Health Service Act pending before Congress this year, is an appropriate vehicle to provide additional assistance. Programs need assistance in funding recruitment drives to attract qualified applicants. Overcoming the fear of contracting AIDS in the laboratory is a major element of a recruitment drive. Programs also need financial support for curriculum development. Presently, the Health Education Assistance Loan (HEAL) program is only available to graduate students.

Moreover, other loan programs authorized under Title VII--Sections 740 and 741 of the Public Health Service Act--are not available to allied health students. At a minimum, these loans need to be made available to all undergraduate allied health professions students. Loan programs targeted to allied health students should be considered.

Conclusion

In conclusion, the ASCP shares concerns expressed by members of Congress regarding the need for quality assurance in the clinical laboratory. We are committed to assisting Congress in this endeavor. Only through cooperation between professional associations such as the ASCP and the government can we ensure that the public is provided the very best in health care delivery.

ATTACHMENT #1

COMPETENCY CHARACTERISTICS OF A CLINICAL LABORATORY DIRECTOR

The clinical laboratory director should be able to:

1. Provide effective and efficient administration of laboratory services including budget planning and control with responsible financial management.
2. Perform strategic planning for setting goals and developing and allocating resources appropriate to the medical environment.
3. Define, implement, and monitor standards of performance concerning the use and value of laboratory services.
4. Communicate laboratory data effectively to physicians, including interpretation for patient diagnosis and management.
5. Function effectively with accrediting, regulatory, local and administrative groups, the medical community, and the population served.
6. Provide educational direction for the medical, laboratory and lay communities.
7. Perform or direct research and development appropriate to the institution.

It is expected that this role will be filled by a pathologist; however, these are the criteria against which any laboratory director should be judged.

Adopted by ASCP Board of Directors June 20, 1986
Revised by ASCP Board of Directors January 24, 1987

ATTACHMENT #2

CERTIFICATION

EXAMINATION

ELIGIBILITY

REQUIREMENTS

MEDICAL LABORATORY TECHNICIAN

Associate degree or equivalent and one of the following:

- **CAHEA accredited Medical Laboratory Technician or Military Medical Laboratory Specialist program, or**
- **Five years of experience**

High school diploma

- **CAHEA accredited Medical Laboratory Technician program and three years of experience**

The medical laboratory technician performs routine laboratory tests in blood bank, chemistry, hematology, immunology, microbiology and urinalysis laboratories under direct supervision.

Medical laboratory technicians may advance to the technologist level by acquiring a baccalaureate degree, appropriate experience and passing the Board of Registry certification examination.

MEDICAL TECHNOLOGIST

Baccalaureate degree and one of the following:

- **CAHEA accredited Medical Technologist program**
- **MLT(ASCP) certification and three years experience**
- **Five years of experience**

The medical technologist performs a full range of laboratory tests from the most routine to the most complex with little or no supervision. A medical technologist can also function as a supervisor, educator, or a researcher.

WRITE TO

For further information and specific requirements for medical laboratory personnel, write the Board of Registry, Box 12270, Chicago, IL 60612

FINANCIAL ASSISTANCE

For information on available scholarships or loans, contact any college or institution offering medical laboratory programs.

ACCREDITATION

For information on accredited programs write the Committee on Allied Health Education and Accreditation (CAHEA), 535 N. Dearborn St., Chicago, IL 60610

CATEGORICAL TECHNOLOGISTS

Baccalaureate degree and one to two years of experience

Many college graduates choose to focus on one field rather than rotating through all laboratory departments. The categories available for certification are:

Blood Banking	Histotechnology
Chemistry	Immunology
Hematology	Microbiology

SPECIALISTS

- **Baccalaureate degree, Technologist certification, and five years of experience**
- **Master's degree and four years of experience**
- **Doctorate degree and two years of experience.**

The medical technologist or graduate level laboratorian may advance to a specialist level by gaining experience in one of the special areas of the laboratory (e.g., chemistry, hematology), and passing the Board of Registry certification examination.

Those areas in which specialist certification is offered include:

Blood Banking	Immunology
Chemistry	Microbiology
Hematology	

There are formal programs available for the Specialist in Blood Banking. Information on these programs may be obtained from

American Association of Blood Banks
1117 North 19th Street
Suite 600
Arlington, VA 22209

HISTOLOGIC TECHNICIAN

High school diploma and one of the following:

- **CAHEA accredited Histologic Technician program or**
- **Two years of experience**

Associate degree or equivalent

- **One year of experience**

The Histologic Technician prepares portions of body tissues from microscopic examination, freezes and cuts tissues, mounts them on slides, and stains them with dyes to make details visible under the microscope.

CYTOTECHNOLOGIST

Associate degree or equivalent and one of the following:

- **CAHEA accredited Cytotechnologist program or**
- **Five years of experience**

Skilled cytotechnologists are needed in pathology laboratories to screen human cell samples under the microscope for early signs of cancer.

The expert eyes of the cytotechnologist trace clues to disease in the delicate patterns of the cytoplasm and nucleus that are stained with special dyes. The work requires patience, precision, and the ability to work alone with minimal supervision.

THE COMMENTS
of the
AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY
before the
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
of the
Senate Committee on Governmental Affairs
of the
UNITED STATES SENATE
on
THE ROLE OF THE FEDERAL GOVERNMENT
IN
ENSURING QUALITY OF CLINICAL LABORATORY SERVICES

American Society for Medical Technology
2021 L Street, N.W., Suite 400
Washington, DC 20036
(202) 785-3311
March 23, 1988

Comments of the American Society for Medical Technology on the Role of the Federal Government in Ensuring Quality of Clinical Laboratory Services, before the Senate Subcommittee on Oversight of Government Management, March 23, 1988.

1. INTRODUCTION

The American Society for Medical Technology (ASMT) is pleased to have been invited to share its views on factors contributing to problems of quality in clinical laboratory services, and what the role of the federal government should be to ensure the quality of clinical laboratory services that the American public expects and deserves.

Founded in 1933, ASMT is the nation's oldest and largest non-registry national professional association for nonphysician clinical laboratory professionals. ASMT's primary mission is to improve the public's health through promoting the efficient and effective use of clinical laboratory services. Our more than 20,000 members include clinical laboratory directors, managers, administrators and supervisors, as well as staff practitioners at all levels of practice. Over 85% of our members possess at least the baccalaureate degree; many of the remainder are students. In addition to practicing in every type of clinical laboratory setting, ASMT members practice as research scientists; as consultants to physicians and institutions establishing or operating clinical laboratories; as educators and deans of allied health; as health policy analysts and as professionals engaged in developing and marketing clinical laboratory diagnostic equipment and products.

In keeping with the breadth and scope of clinical laboratory science, ASMT members are known by a variety of designations, depending upon their areas of specialty. Some of the more common designations include clinical laboratory scientist, medical technologist, clinical chemist, microbiologist, hematologist, immunohematologist, cytotechnologist, histotechnologist, nuclear medicine technologist, medical laboratory technician and phlebotomist.

At the very core of ASMT's raison d'etre is its commitment to the principle that the quality of clinical laboratory services is only as good as the quality -- that is, the competence -- of its practitioners. Since its inception 56 years ago, ASMT has been consistently in the leadership of the profession in founding and sponsoring programs to ensure the quality of clinical laboratory science education and the competence of clinical laboratory practitioners.

In 1973, ASMT collaborated with the American Society of Clinical Pathologists (ASCP) in establishing the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), an autonomous agency responsible for reviewing and accrediting the nation's university and hospital-based medical technology (MT), and medical laboratory technician (MLT), and histotechnology education programs. Since then, ASMT members (independently and as representatives of the Society) have continuously assisted NAACLS in defining and implementing the principles by which professional education programs can appropriately be accredited.

ASMT has also led the profession in establishing programs to ensure entry-level and continuing competence of clinical laboratory scientists. In 1977, ASMT founded, and currently it sponsors, the National Certification Agency for Medical Laboratory Personnel (NCAMLP). NCAMLP (hereinafter, NCA) is the nation's second-largest clinical laboratory practitioner credentialing body. NCA currently offers credentialing examinations for eight levels of practice (including clinical laboratory director). Since its founding, NCA has certified some 49,393 practitioners.

ASMT wishes to emphasize that NCA is the only national certification program in this profession that requires demonstrated evidence of continuing competency, through a mandatory recertification procedure. This requirement demonstrates ASMT's conviction that the practitioner's qualifications are the bedrock that assures service delivery quality. It also underscores our conviction that initial certification alone does not guarantee practitioner competence in perpetuity, particularly in sciences utilizing advanced, constantly evolving electronic, mechanical and biological technologies.

To these ends, ASMT and its 52 constituent societies also provide a host of continuing education programs each year, in the form of scientific and technical sessions and workshops at their national, regional and state annual meetings. ASMT also offers peer-reviewed, self-administered continuing education modules in its journal Clinical Laboratory Science, and publishes a variety of scientific, technical and professional publications.

Indeed, ASMT's Competence Assurance Documents, originally published in 1981, after more than a decade of extensive technical research, are widely regarded as the definitive articulation of the profession's scope of practice and of the knowledge bases, skills and abilities that comprise its body of knowledge. Revised and updated to reflect changes that significantly affect the profession, these documents include: (1) The Body of Knowledge and Task Delineations (570 pp., 1986 rev.); (2) Model Criteria for Peer Review and Standards of Practice (250 pp. 1981); (3) Levels of Practice (1988 rev.); (4) Performance Objectives (455 pp., 1987); (5) Criterion-based Personnel Management (1988); (6) Scope of Practice (1980), and (7) Statements of Competence (1987 rev.) Together, these publications guide educators, managers and personnel administrators worldwide in developing and administering criterion-based clinical laboratory management tools.

Finally, ASMT is actively involved in a number of other organizations dedicated to upholding highest standards of quality for clinical laboratory practice. ASMT is an institutional member of the National Committee for Clinical Laboratory Standards (NCCLS), which develops product, procedure and practice standards for the clinical laboratory. Additionally, ASMT participates through official representatives on the Advisory Committee of the Nuclear Medicine Technology Certification Board (NMTCB) and the Joint Review Committee for Education in Nuclear Medicine Technology.

These activities and ASMT's active participation in the promulgation of federal and state clinical laboratory law and regulation over more than three decades, uniquely qualify ASMT to offer its views on the current status of laboratory regulation and the role that the federal government can and should play to better ensure acceptable laboratory quality.

2. THE EXISTING FEDERAL REGULATORY SCHEME HAS FAILED TO ENSURE UNIFORM DELIVERY OF QUALITY LABORATORY SERVICES IN ANY SECTOR OF THE SERVICE DELIVERY MARKET.

Since the mid-1970's, when we testified before many congressional panels, ASMT has been both a strong proponent of appropriate, mandatory federal regulation of clinical laboratories, and a consistent critic of the existing federal (and state) regulatory structure. What we said during "CLIA" days we can only reiterate today: a regulatory structure that is predicated on test sites needlessly necessitates separate laws and regulations for laboratories based on their location; builds in costly and confusing compliance and administrative costs; and is inherently flawed. Such a structure neither can nor should be approached as if it can be fixed "piece-meal," with a tinker here and a tinker there. Rather, it should be subjected to a thorough and logical, comprehensive reform.

As ASMT and numerous other commentors have noted, the current federal regulatory structure is grossly flawed. First, since it was adopted in the mid-1960's, it is based upon seriously out-of-date technologies. Quality control requirements that might have been appropriate 20 years ago are irrelevant to today's laboratories. Moreover, the micromanagerial approach such regulations typify (by spelling out in infinite detail the smallest components of instrument-specific quality control measures) frustrates rather than encourages good management and builds in the inevitability of future revisions that could be avoided if the regulatory emphasis were upon output measures of quality rather than too-specific input measures. What is required, we feel, is a balanced combination of the two.

Second, the current structure still relies on a flawed approach to proficiency testing. Rather than ensuring a fair, meaningful proficiency testing method, it merely describes what a given laboratory can do under the most ideal testing circumstances. It has little, if anything, to say about real proficiency in real-world circumstances.

Third, since it is predicated on the site in which a test is performed, it virually ensures awkward, costly regulatory duplication in some instances and contradiction in others. That is, the premise requires three separate regulations when one well-thought-out regulation would suffice.

Fourth, as the distinguished panel well knows, it unjustifiably exempts physician office laboratories from regulation. These facilities account for a sizeable volume of tests performed today, and it is believed they will capture a still larger share with the evolution of more, and less costly, "desk-top" technologies, particularly if certain financial incentives embedded in federal approaches to healthcare cost-containment are continued.

These are common criticisms of the federal approach to regulating clinical laboratories. Other criticisms are at least as serious. First, as William Roper, M.D., Administrator of the Health Care Financing Administration (HCFA) himself testified, HCFA has sustained a 30% cut in its operating budget, at the same time it has faced a storm of criticism about laboratory quality, and at the same time that the agency has been faced with requirements to prepare an unusual volume of new regulations pertaining to the payment of clinical laboratory services. Like many another domestic program, HCFA has been told unrealistically to do more with less, and so have our nation's clinical laboratories themselves, under the repeated assaults of fee schedules and limitations on fee schedules for clinical laboratory reimbursement under Medicare.

Second, as others elsewhere have noted, the sanctions available to the Program for enforcing known violations of existing standards are not adequate. Problems include a lax attitude toward enforcement, for starters, but also a maze of red tape that means, substantially, that facilities in serious violation of federal standards can operate, and go on operating indefinitely, with impunity.

Next, there has been an apparent tendency in recent months to address the shortcomings in the regulatory maze by adding to the maze, and, it might be said, by developing new proposed regulations by disease or impairment state, rather than on the basis of need and logic. That, at any rate, is one of our chief criticisms of the approach adopted by the National Institute on Drug Abuse (NIDA) relative to regulating laboratories engaged in urine drug testing for federal employees.

Finally -- existing law and regulation do not adequately safeguard the public from the imposition of privately-promulgated, self-serving and anticompetitive standards in the guise of quality assurance safeguards.

Under the expanded authority provided the HHS Secretary in Section 2346 of the Deficit Reduction Act of 1984 (DEFRA), the Secretary may rely more extensively than before on private-sector accredit entities to inspect and accrediting healthcare facilities for Medicare program participation.

Both the Clinical Laboratory Improvement Act of 1967 and the Health Insurance for the Aged Act provide for the transfer of the federal healthcare facility accreditation authority to "equivalent" programs. CLIA authorizes the exemption of laboratories that are licensed by states or accredited by independent agencies that establish standards that are at least equivalent to CLIA's. Among state programs, only that of New York State has thus far earned "equivalency" status under CLIA. Among private programs only CAP's program has been recognized by CDC as equivalent to CLIA's. Thus, an interstate laboratory seeking to meet CLIA requirements can do so only through meeting CLIA's own requirements or through meeting CAP's requirements for the laboratories it inspects and accredits.

As for the Health Insurance for the Aged Act which established Medicare, Title XVIII (the Social Security Act) includes a statutory provision recognizing hospitals accredited by JCAHO and the American Osteopathic Association (AOA) as deemed to have met Medicare requirements for hospitals. As yet, only JCAHO and AOA are thus recognized, and JCAHO has entered into a special "subdeemed status" arrangement with the College of American Pathologists (CAP) under which laboratories in hospitals may be inspected by CAP's Laboratory Accreditation Program (LAP) and, if accredited, need not be re-inspected by JCAHO.

As for independent laboratories not regulated under CLIA, the Medicare statute does not authorize the HHS Secretary to delegate this critical regulatory function to state or independent (private-sector) programs. These independent laboratories must be Medicare certified. Unless they are engaged in interstate commerce and are CLIA regulated, there is no alternative.

As the distinguished panel knows, for several years, the College of American Pathologists (CAP) has sought direct authority under Medicare, whereby laboratories inspected and accredited by CAP's LAP would automatically be deemed to have met Medicare coverage conditions. Since CAP already has this authority under CLIA for interstate laboratories, and (under a subdeemed status relationship with JCAHO) for laboratories located in hospitals accredited by the Joint Commission, if CAP were to achieve direct deemed status under Medicare, CAP's LAP would become the only non-federal clinical laboratory inspection and accreditation program authorized to accredit laboratories in all settings for Medicare reimbursement.

Proponents -- noting budget cutbacks -- argue that such a plan would enable Medicare to farm out its inspection responsibilities to qualified private-sector entities.

While ASMT strongly and consistently supports reasonable, appropriate cost-containment strategies, the Society adamantly opposes expanded deemed status for CAP as anticompetitive, ill-thought-out public policy, and, ultimately, as a sure-fire cost escalator.

In the first instance, while CLIA and Medicare permit qualified nonphysicians to direct full-service clinical laboratories in all settings, CAP, under new standards promulgated this past summer, requires that physicians, and only physicians, and preferably, pathologists, direct clinical laboratories in all settings, regardless (in CAP's own words) of location, ownership or setting of the laboratory. Although CAP nods at "exceptional circumstances" in which other than a physician/pathologist could direct a CAP-accredited laboratory, it neither defines those "exceptional circumstances" nor provides interpretation. For all intents and purposes, CAP requires all laboratories to be physician/pathologist directed.

As ASMT has pointed out many times, granting deemed status to CAP would, in effect, substitute CAP's self-serving, pathologist-only director requirement for Medicare's own pro-competitive director standards--with no justification in terms of quality, and without regard for the attendant consequences in terms of direct and indirect personnel costs.

Second, it should be noted that CAP's most recent 1987 standards are the first revisions since sweeping regulations were enacted by HCFA that differentiate for Medicare payment purposes between physician services and nonphysician services. It should come as no surprise, then, that the new CAP standards incorporate as physician /"director" functions every salient function that was defined in the "TEFRA hospital based physician reimbursement regulation" as a function that neither requires nor customarily receives performance by a physician. We therefore believe that CAP is attempting to achieve through deemed status what is could not achieve in law or in a subsequent court ruling of TEFRA--namely, physician/pathologist domination of a function that Medicare, CLIA, the federal appellate court, and four state attorneys general have said clearly is not the practice of medicine.

Third, the new CAP standard was promulgated at a time when many clinical laboratory services are moving out of the hospital sector (where the vast majority of pathologists are employed) to nonhospital laboratories that compete directly with them and that, significantly, are frequently directed, owned and operated by nonphysicians. Again, as ASMT has pointed out elsewhere, a close comparison of the findings of the TEFRA regulation (upheld against a CAP challenge by both the district and the appellate courts in the District of Columbia circuit) with the 1987 CAP standards discloses a remarkable coincidence: that whereas until 1987, even CAP itself permitted qualified nonphysicians to direct full-service independent clinical laboratories, now, since the TEFRA ruling, even independent laboratories must be physician/pathologist directed if they are to be CAP-eligible.

As we have argued extensively elsewhere, ASMT believes this CAP director standard to be blatantly anticompetitive. If given additional stature through a grant of deemed status, CAP's LAP can and most certainly will attempt to impose its own self-serving personnel standards upon the taxpayer and the private purchaser of healthcare services alike.

Apart from the anticompetitive potential of the CAP standards -- a potential noted also by the Federal Trade Commission and by Congress itself in the conference report accompanying section 2346 of DEFRA -- is the fact that relegating the federal government's regulatory and enforcement authority to the private sector is an extraordinarily risky and, we believe, poor policy. As ASMT has noted elsewhere, the statutes governing both CLIA and the Medicare program do not contain adequate safeguards against the kind of anticompetitive special interest the CAP standards embody. That is, these statutes do not they prohibit a private-sector entity such as the College from promulgating and imposing through the deemed status mechanism its own self-serving standards.

Moreover, CAP itself has publicly stated that its Laboratory Accreditation Program is "not a regulatory program." (Wall Street Journal, February 2, 1987, page 2) Unfortunately for a public that is dependent even now on CAP for quality assurance enforcement (through the CLIA and the JCAHO authorities), CAP's LAP is responsible for performing an inherently regulatory function, whether it wishes to do so or not. Should that public trust be extended through broadening CAP's deemed status authority, the public-- including payers of all types and those whose lives may depend on federal quality assurance regulation and enforcement-- can only be placed at broader risk.

This becomes clear when it is recognized that CAP, by its own admission, has "revoked the accreditation of just one of 3,800 laboratories [it has inspected] since January, 1985.]"

While HCFA and CDC should be asked to provide a detailed accounting of the numbers of clinical laboratories that are inspected directly and by deemed status arrangements, and the numbers with deficiencies of all kinds, and the numbers that have been subjected to all available types of penalty, including decertification, our members note from personal experience that the process used by CAP in inspecting and accrediting laboratories can and does often leave much to be desired.

In the first place, CAP's accreditation and inspection standards are not uniformly applied. This is a significant failing in a program that is implemented by a federal agency that is under statutory and/or regulatory obligations to implement and enforce Medicare quality of care standards. According to information provided by individuals who are laboratory directors or administrators and who have witnessed CAP inspections, the process can vary from extremely rigorous to extremely lax-- almost lackadaisical -- may be in part because CAP's LAP relies on volunteers from neighboring laboratories to perform its inspections. It should not stretch the imagination to note that kind of volunteer arrangement, particularly when neighboring labs are involved, can easily degenerate into "you scratch my back, I'll scratch yours" inspections, and indeed, we hear this criticism of the CAP LAP process frequently.

This sort of indecisiveness on CAP's part has significantly contributed to the widespread confusion and consternation caused among hospital and clinical laboratories by CAP's issuing its new standards. And, we wish to note for the record that nothing in the federal deemed status authorities precludes private-sector entities from doing what CAP has done: that is, changing its standards, at will, without notice or justification. This, clearly, is another reason why we feel reliance on private-sector entities like CAP is a poor public policy.

Moreover, the variability of the CAP process extends not only to inspections of clinical laboratories within, say, a given city. It also extends across types of laboratories. At a recent symposium on clinical laboratory regulation, Dr. John Duckworth, formerly Chairman of CAP's and a figure instrumental in the formulation of CAP's LAP standards, remarked that while CAP intends to enforce its director standard it hospital laboratories, it does not intend to do so in independent laboratories. It will be recalled that one of the most salient characteristics of the new 1987 CAP standards is CAP's deliberate expansion of the physician/pathologist director requirement to independent laboratories, for the first time. Given that fact, it stretches the imagination to accept that CAP would first write and then fail to enforce that standard -- particularly in light of the competition imposed by independent laboratories on hospital laboratories (noted earlier).

But even setting aside legitimate skepticism, CAP's statement that it intends a variable interpretation of its standards (a) raises serious policy questions about the wisdom of deeming CAP(and other private programs) until and unless appropriate safeguards are instituted, and (b) surely sets the College on a collision course with applicable federal law and regulation governing the implementation and enforcement of private standards when they serve in the stead of federal standards.

Finally, from the perspective both of approving CAP's request for deemed status and from the perspective of the kinds of dilemmas that can arise when the federal government relies without proper safeguards on private sector programs like CAP's, it is significant that CAP's current caseload is reportedly not adequately being managed.

The Department and the College should be asked to provide data on the timeliness with which CAP inspects and accredits its current laboratory caseload. For instance, according to our sources, CAP is already from 6 to 9 months late in performing laboratory inspections for even mainstream facilities. That figure jumps, reportedly, to one to two years late when it comes to CAP's inspection of laboratories in the Indian Health Service. Such delays obviously jeopardize the quality of laboratory operations. Thus, before the Department delegates its healthcare quality regulatory and enforcement responsibility to CAP, it should ensure that CAP can fulfill that role. The conference report accompanying DEFRA section 2346, in fact, says explicitly that an accrediting organization "must have a satisfactory record of application of [its] standards.

CAP has yet to prove such a record. But the Department itself has indicated that, should CAP win deemed status, its current caseload could more than double. At present, it accredits some 40% - 45% of hospital laboratories, to say nothing of its CLIA caseload and the laboratories it inspects and accredits under state deemed status arrangements. However, where formerly CDC reinspected some 10% of CAP accredited facilities to determine compliance with CLIA requirements, it is our understanding that today that figure has dropped to 1 to 2 percent. We do not know whether or to what extent the Department monitors CAP's accreditation performance under CAP's "subdeemed-status" arrangement with JCAHO, but in all probability, that too, has declined sharply over time.

Whatever the case, we feel strongly that the federal government cannot delegate quality assurance regulation and enforcement, and should be dissuaded from doing so. The CAP case ia a clear example of the kinds of problems that inevitable will arise. And we wish to underscore that CAP's deemed status application is but a test-case of a policy that is under consideration for many other healthcare facilities.

3. WHILE THE MAJORITY OF CLINICAL LABORATORY SERVICES IS COMPETENTLY PROVIDED AT CONSISTENTLY ACCEPTABLE (OR BETTER THAN ACCEPTABLE) LEVELS OF QUALITY, THE CURRENT REGULATORY APPARATUS ALLOWS A GROWING VOLUME OF LABORATORY TESTS TO BE PROVIDED UNDER SUB-STANDARD QUALITY ASSURANCE CONDITIONS.

Conventionally, a clinical laboratory is defined as:

> a facility for the examination of materials derived from the human body in order to provide information for the diagnosis, prevention, and treatment of disease or disorder, and to assess and maintain health and wellness.

Full-service clinical laboratories typically provide anatomic pathology, microbiological, chemical, serological, histological, hematological, cytological and immunohematological services.

Estimates of the number of facilities providing some or all of these services vary, particulary in the case of physician office laboratories (POLs) which have been estimated at as few as 40,000 and more than 100,000 facilities. However, recent estimates from the Office of the Assistant Secretary for Planning and Evaluation, and the Health Care Financing Administration (HCFA), appear to indicate that the Department believes that there are about 12,000-14,000 federally regulated clinical laboratories that are subject to the provisions of one or more of the following:

(a) The Clinical Laboratory Improvement Act of 1967;

(b) The Medicare Conditions for Coverage of Services of Hospitals;

(c) The Medicare Conditions for Coverage of Services of Independent Laboratories.

As ASMT submitted in numerous congressional hearings on laboratory quality during the 1970's, and as we again submit today, these regulations are not without serious flaws. However, (1) because inherently they recognize that voluntary compliance with established standards does not and never has sufficed to assure quality, and (2) because they predicate laboratory quality assurance on personnel, proficiency testing and quality control requirements, these provisions are the most significant factor in the high quality of clinical laboratory care enjoyed in this country today. The accuracy, reliability and validity of tests performed by the majority of these federally regulated facilities are provided at the highest levels of quality.

Recent 1987 data indicate that some 75% of 200,000 surveyed U.S. physicians perform in-office diagnostic laboratory tests. If accurate, this means that there are some 150,000 POLs, most of which are unregulated. Although the recommendations that follow call for a fundamental and thorough restructuring of regulations for laboratories in all settings, ASMT believes the gravest problems of quality are to be found in the POL sector.

As ASMT noted in its pioneering 1986 study of the quality of POL clinical laboratory services (copy attached) POLs are diverse in size as well as in the volume and sophistication of testing they provide. They range from single-physician offices in which the physician alone provides the testing, to group practices involving hundreds of physicians equipped with automated, computerized facilities comparable to the most advanced hospital laboratory. (ASMT White Paper, "Quality Assurance in Physician Office Laboratories: The Setting, The Issues, and Federal, State and Private Approaches, 1986, p. 1.)

Typically, under the terms of the few state laws that regulate them, POLs with five or fewer physicians are generally exempt from state regulation. If they perform tests solely for the physician's own patients, provide fewer than 100 tests on referral in a given clinical specialty area per year, and do not hold themselves out as available to perform tests for other physicians, POLs are also currently exempt from federal regulation regardless of the volume of services or sophistication of laboratory tests they perform.

ASMT has consistently opposed the regulatory exemption of POLs, arguing during the "CLIA" hearings of the mid 1970s, and even earlier that the site in which a test is performed is prima facie irrelevant in determining whether minimum quality assurance standards should apply. Unfortunately, physicians who opposed regulation of in-office laboratories prevailed upon Congress to continue the exemption of POLs from the federal regulation approaches set up in the mid-1960's with the advent of Medicare/Medicaid.

Since then, as the following comments demonstrate, the case for rational, mandatory regulation of laboratories in all settings has grown geometrically, as has the number of tests performed in that sector -- a fact which Congress itself recently recognized through enacting a requirement that, effective January 1, 1991, POLS that provide more than 5,000 clinical laboratory tests (Medicare and non-Medicare) per year will be subject to the Conditions of Coverage for Independent Laboratories. (Cite omitted.)

Congress at last took note of growing public outcry against poor laboratory test results. Contemporary expressions of consternation about the quality of laboratory services began in earnest in February, 1987, with a Wall Street Journal "expose," were further expressed by local investigative TV reporter Lea Thompson, and have only multiplied since. Among their legitimate points are, in ASMT's view, the indictment of the "surreal tangle" of state and federal laboratory regulation; the lax enforcement thereof; and the negligent reliance on un- and inadequately-trained personnel in unregulated laboratory settings. As the Wall Street Journal put it:

> The recent surge of testing in doctor's offices is particularly troubling, critics say, because these . . . facilities are often entirely free of regulatory oversight. . . . . As a result, in all but a handful of states, their personnel needn't meet any training standards. Dr. [Paul] Fischer, the authority on office laboratories, says that in as many as two-thirds of small doctor's office labs, work is done by employees lacking formal lab training, including medical secretaries and receptionists. (Walt Bogdanich, "Medical Labs, Trusted as Largely Error-Free, Are Far From Infallible," Wall Street Journal, February 2, 1987 pp. 1 and 18.

These are substantially the same points emphasized in ASMT's 1986 POL study. Briefly, ASMT found that the larger the POL, the likelier it is to retain qualified, professionally-educated practitioners in staff and supervisory positions, whereas the smaller the POL, the likelier it is to rely upon any individual at hand -- e.g., the physician's cousin or nurse -- to collect specimens involved in, and to perform, interpret and report sensitive and complex laboratory analyses. In short, it is precisely those POLs that are most evidently in need of mandatory quality assurance standards that are most likely to be exempt from them.

Unfortunately, if anything has changed since the days of the "CLIA hearings," it is that the ground underlying POL testing is far more fertile now. As ASMT's study revealed, technological developments (principally, advancements in microprocessing) have made "desk-top" laboratory diagnostic instruments affordable for small POLs at exactly the time when the primary economic incentives embedded in Medicare's new PPS payment system have acted to drive testing out of the regulated hospital laboratory sector, and into the unregulated POL.

Physicians, beset by Program payment for cognitive procedures that are generally agreed to be inappropriately low; by a federal government increasingly aware of the need to constrain physician payment under Medicare/Medicaid, and by maniacal malpractice premiums (among other stimuli, including a desire for quicker turn-around and enhanced patient convenience) have responded by establishing or expanding in-office testing capabilities. Moreover, estimates are that POL testing will increase in volume unless the 1988 POL regulation clause withstands the predictable avalanche of opposition that has already been launched, and the state and the federal government bring POLs under mandatory regulation. Unless these occur, the problems of quality attributed principally to physicians' reliance on un- and inadequately educated practitioners and to physicians' own relative ignorance of the complexities of laboratory quality assurance protocols, can be expected to multiply.

In preparing for this testimony, ASMT has surveyed many of our members who are employed as consultants for physician office and independent labs or who act as representatives for various laboratory equipment companies. We have asked them to provide information on the three major problems they encounter in POLs on a daily basis. Almost universally, our members have cited (1) lack of qualified personnel, (2) lack of quality control procedures and (3)inadequate outcome assesment through proficiency testing. Ironically, these are the three elements ASMT testified about during the CLIA hearings and that were deemed to be central aspects of the CLIA legislation.

Although many larger group practices employ medical technologists, the majority of physician offices, employing one to five full time physicians, staff their laboratories with non-degreed technical personnel. ASMT White Paper on POLS at 15, citing, Frost and Sullivan, Inc., "Group Practice Laboratories Benefitting from New Federal Regulations,", News of International Research Reports for Business, Summer, 1985. One study revealed that in solo practices, nurses and "other" office staff are most likely to perform office testing. Id, citing Georgia Department of Human Resources, "A Statewide Survey of Office Laboratory Practices Among Members of the Medical Association of Georgia", 1982.

Additional studies demonstrate that unqualified personnel are also performing the majority of tests in group practice POLs. For example, a 1982 survey of 199 POLs in Ohio and North Carolina revealed that less than 30% had certified laboratorians performing the tests. Gwyther RE, Kirkmann-Liff BL, "Laboratory Testing in the Offices of Family Physicians." AM J. Med. Tech. 48:697-702 (1982). This same literature reports instances of lab tests being performed by secretaries, nurses untrained in lab procedures, physician's relatives, and high school students.

Recent studies also demonstrate a correlation between the level of skill of the practitioner performing the test and the quality of test result. A series of studies published in the Journal of American Medical Association concluded that medical technology education correlates with improved quality of laboratory results. Using proficiency test results as a measure of quality assesment, one study revealed that labs using all certified medical technologists had an accuracy rate of 95%; while those using all non-certified medical technologists had an accuracy rate of only 75%. Lunz ME, Castleberry BM, "The Impact of the Quality of Laboratory Staff on the Accuracy of Laboratory

Results", JAMA 258:361-363 (1987). Even more alarming is a series of studies which concluded that new laboratory technology when operated by medical technologists was found to be accurate, precise and generally reliable. However, when the same technology was operated by individuals without formal lab training, the variability of the results was found to be significantly greater. Belsey, Goldstein, Baer, "Evaluation of a Laboratory System Intended for Use in Physicians' Offices," JAMA 258: 353-356, 354-361 (1987).

Comments we have received from ASMT members confirm these findings. Time and again we have heard that laboratory tests, regardless of complexity and need for technical expertise, are being performed by individuals untrained in laboratory work, including physicians, nurses, secretaries and relatives. Advanced technologies and computerization has only exacerbated the problem by giving physicians a false sense of security. For example, ASMT has heard of an internist in the Midwest who, using a highly sophisticated computerized cholesterol screening machine, provided patients with a five year prognosis on the basis of what the machine reported, without taking into account the limitations and methodology of the instrument.

Despite technological advances, even the most simple tests, such as a urinalysis, are routinely misinterpreted. One member told of a OB/GYN office that failed to diagnose a urinary tract infection, even though a microscopic examination of the specimen revealed four times the normal amount of white cells. In another office, the unnoticed expiration date on urinary dipsticks caused a surge of false positive results leading healthy women to be improperly diagnosed as having urinary tract infections. In both cases, the cost of care increased and the patients' quality of care was compromised.

Microbiology tests, involving the use of incubators to allow cultures to grow, are consistently performed improperly by untrained personnel. One member reported seeing both a POL and an independent lab using a makeshift incubator, consisting of a cardboard box and a light bulb, to attempt to simulate a body temperature of 37°C. Not only is this a poor practice, but they also failed to monitor the temperature by using an internal thermometer. Another physician, who used the "scientific" method of sticking his hand in the incubator to "monitor" the temperature, complained to one of our member consultants that the state health department must have sent him a bad batch of Streptococcus cultures since they weren't growing anything. She then overheard him telling a young patient's parents that the child's Strep culture was negative, despite his continuing illness. If he couldn't grow the state's culture how was he to properly identify the cause of this child's illness?

Quality assurance and controls, which are the only way to ensure reliability and accuracy of testing, are almost completely lacking from POLs. Our members contribute this to cost conscious physicians, most of whom have had little if any training in laboratory procedures, and have been mislead into believing that quality assurance will reduce profitability and is unnecessary on "maintenance free" equipment. AMST members report that documented procedures for performing testing are conspicuously absent in most POLs, and that on the job trainees are often themselves trained by unskilled and unqualified personnel.

Published studies show a correlation between the skill of the individual performing a laboratory test and the likelihood that the laboratory will perform quality assurance procedures. See Gwyther supra, (78% of practices using certified technicians had quality control programs while only 21% and 15% respectively, of practices using non-laboratory trained physicians had quality control programs).

Thus, it is not surprising that one of the most common problems encountered by ASMT member consultants and industry representatives involve the failure to run standards and controls and to perform regular equipment maintenance. We have heard of personnel failing to change reference ranges with a new lot of reagents, of a kidney specialist who performed sophisticated protein and micro-protein tests without ever running controls, and of a nurse practitioner who left off a standard in performing a liver enzyme test, which resulted in a missed diagnosis and led to an outbreak of Hepatitis A in a small, mountain community.

Proficiency testing, except in the few states that regulate POLs, is virtually unheard of. A recent external quality assurance study performed by the Nebraska Society for Medical Technology (NSMT)(copy attached) confirms that there is substantial cause for alarm about the quality of laboratory performance in POLs. The study revealed that 55% of the blood chemistry samples tested by participating POLs were outside of the acceptable range, as compared to 13% of the samples tested by the control group, JCAHO or CAP accredited labs. The test results of the hematology and urinalysis samples are similarly alarming. 47% of the POLs hematology results were outside of the acceptable range and 10% of the urinalysis results were unacceptable. On the hematology sample, 28% of the control group's test results were outside of the acceptable range. This again raises the question of the ability and propriety of delegating laboratory accreditation and quality assurance review to the private sector.

Improper performance of laboratory tests, misinterpretation of results and misdiagnosis exacts a tremendous price on society---not only on our general welfare, but also in terms of health care dollars. How often are unnecessary, additional laboratory tests run because of a simple, avoidable error in a routine test? One ASMT consultant reported that repeated questionable results from a hemoglobin test caused a family physician to routinely order costly blood tests which were analyzed by an outside lab. Our member discovered that the nurse practitioner who performed the tests had misread the stain bottle, and was staining smears for three minutes instead of thirty seconds, thus causing normal cells to appear to be abnormal leukemia cells.

4. CENTRAL TO THE PROVISION OF LABORATORY SERVICES OF ACCEPTABLE QUALITY COST AND EFFECTIVENESS ARE APPROPRIATE STANDARDS FOR PERSONNEL AT ALL PRACTICE LEVELS.

ASMT has repeatedly urged lawmakers to recognize that the quality of laboratory services depends above all on the competence of those who perform them:

> We cannot emphasize too strongly the necessity for competence in those actually performing the testing. The complexity of present-day laboratory methodology is such that even so-called "simple" or "routine" analyses, usually performed by technicians, require a significant degree of skill and knowledge; likewise, the more complex responsibilities of technologists, who function more independently and who must exercise judgment based on theoretical knowledge as well as perform with technical competence. . . .It cannot be assumed that competent performance can be assured through supervision along (cite omitted.)

And yet, knowledgeable sources report that HCFA may be proposing (1) to delete personnel standards below the director level, ostensibly as part of an in-process streamlining and consolidation of federal laboratory regulations, and (2) is considering granting CAP deemed status, which as previously discussed, would vastly increase the applicabilty of CAP's anticompetitive director standard. ASMT urges this distinguished Subcommittee to ensure the promulgation of appropriate standards for personnel at all practice levels, and further calls on our states to establish mandatory licensure for laboratory professionals. Inherent in our view is the concept that an "appropriate" personnel standard is one which is reasonably based on the task of being performed and -- especially in the present cost-containment era--one which enables qualified competition and permits the cost-effective deployment of personnel at their highest level of competence.

In the comments that follow, ASMT offers in outline form a radically new but eminently logical recommendation for how such regulation can be achieved in a manner that also recognizes that there are legitimate practice distinctions among laboratories of various kinds, which do require different regulations.

Paul Starr, MD, in The Social Transformation of American Medicine (1982), recently detailed the evolution of a profession--we think persuasively. During the 56 years in which ASMT has sought to uphold and improve quality of clinical laboratory services, nonphysician laboratory practice has developed from a truly ancillary level to a bona fide science in its own right. As ASMT has frequently pointed out, this fact has been recognized at least since the institution of the Medicare/Medicaid programs by the federal government. All pertinent federal law and regulation recognizes a distinction between the practice of medicine and the practice of clinical laboratory science. The federal government established that recognition first in promulgating personnel standards that permit qualified nonphysicians to direct full-service clinical laboratories in any setting -- an action which it could not have taken (logically or lawfully) were the rendering, interpretation and reporting of test results part of the practice of medicine. And it emphatically reaffirmed that finding, which is shared by attorneys general in at least four states, in the enactment of the Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248) and its subsequent regulations.

With the exception of certain procedures that either depend upon performance in person by a physician for the benefit of a specific patient, or were defined for purposes of Medicare Part B payment as "physician service," by far the vast majority of tests performed in the clinical laboratory neither require nor receive any attention from the pathologist. See, 42 Fed Reg 48.8902 ff.

Although CAP sought to permanently enjoin the so-called "TEFRA Rule" both the District and the appellate court in the District of Columbia circuit upheld those and similar findings that underpinned the Department's critical distinctions between services that do and do not require physician involvement for Medicare payment purposes. (College of American Pathologists v. Heckler, (Cites omitted) It is important to note that arguments submitted by the Department of Health and Human Services (HHS) and by ASMT in successful support of that final rule estimate that approximately 98% of laboratory tests require no physician involvement whatsoever beyond that of the attending physician who orders them -- even when the results are well outside the expected range given the patient's clinical condition. Brief of Amicus, ASMT, in CAP v. Heckler (cites omitted).

For these and other reasons documented extensively in that record and elsewhere, ASMT therefore defines clinical laboratory science as:

> encompassing the performance, interpretation, reporting and clinical correlation of clinical laboratory tests. . . through applying the scientific principles of biology, chemistry and physics as they relate to physiologic and biochemical process in the human being. The clinical laboratory profession also incorporates principles of social science to serve its primary purpose. (ASMT White Paper, "Independent Practice in Clinical Laboratory Science," May, 1987.)

Indeed, in a white paper provided for a recent symposium on the question of the viability of independent practice by allied health professions (copy attached), ASMT maintained that independent practice in clinical laboratory science not only is probable, but has already begun. It should be self-evident then, that, conventional or independent, if they are to be done competently, such functions require performance by individuals who are professionally educated and trained -- or who, through properly constructed, appropriately validated proficiency examinations can demonstrate the sound, reliable acquisition of these essentials on the job or through combined education and on-the-job training. At the same time, such regulatory requirements need not be, and should not be, monolithic. On the contrary, ASMT believes that they cannot be, if they are to be either optimally effective or feasible, and makes this view clear in the comments that follow.

5. ASMT PROPOSES A NEW REGULATORY SCHEME ENCOMPASSING SITE NEUTRALITY, CORRELATION BETWEEN COMPLEXITY OF TEST TECHNOLOGY AND LEVEL OF PERSONNEL QUALIFICATIONS AND TOTAL QUALITY MANAGEMENT

ASMT believes that the present system of laboratory regulations is in need of reform. New regulations are needed to assure the quality of the large and growing number of tests performed in POLs. On the other hand, regulatory relief is needed by hospital and independent laboratories which must conform to the quality control standards designed for an era when manual testing methods predominated and reagents and media were not commercially available.

In response to these quality issues identified earlier and to the need for reform, our organization proposes the ASMT Regulatory Model:

> Laboratory regulations (quality control, personnel standards, and proficiency testing requirements) should be based upon the complexity and quality of the test methodology, independent of the laboratory performance site, and applied to all testing locations. The principles of Total Quality Management of Laboratory Services must guide the development and implementation of such regulations. ASMT believes that three principles must be central to attempts at regulatory reform:

a) It is necessary to assure the quality of ALL laboratory test -- independent of site of performance.

Under current federal regulation, the same test performed by identical methods can be subject to different regulatory requirements based upon the performance site. You have heard testimony which affirms the quality problems which exist in decentralized testing locations. We believe that patients have a right to, and their health requires, the same high quality of testing regardless of performance site. Therefore, the ASMT model includes a consolidated and universal regulatory approach to be uniformily applied to all laboratory settings and locations.

b) Laboratory regulations must be linked to the complexity of quality of the test technology and degree of independent judgment required to provide that test service.

Under the current regulatory model used in Pennsylvania and Massachusetts, the regulatory principle takes into account different types of tests, but ignores one of the fundamental determinants of test quality and reliability: the quality and complexity of the instrument and methods used in test performance. However, there are many serious problems that arise when determining which tests to include and exclude from the limited laboratory license category. Many tests can be performed with several different types of technology -- some relatively simple to perform, others extremely complex. To blanketly include a test, while not tying it to a specific technology or method, would run the risk that a laboratory would select a method too complex for its personnel. Conversely, to exclude a test because some of the test methods are not acceptable, would deny access to convenient and timely laboratory testing. Therefore, the ASMT model is based on the complexity and quality of the test method.

c) All laboratory regulations must be considerred within the context of Total Quality Management of Laboratory Services.

Total Quality Management of Laboratory Services is a concept developed during the last two years under the leadership of the Centers' for Disease Control Training and Laboratory Programs Office. Quality of testing begins before the test is performed and continues through the measurement and interpretation of the test result. Improving laboratory utilization, and hence laboratory quality, requires the assurance that the appropriate test is matched with the clinical question and that the total test process is conducted in an efficient and effective manner. This broader context of regulatory reform will require applied research and demonstration projects to determine an appropriate method to adapt, and possibly expand, regulations to include Total Quality Management of Laboratory Services.

Within the ASMT regulatory model, we propose three categories with associated regulatory standards. Level One would be restricted to test methodologies performed on highly automated and internally calibrated devices requiring very limited technical expertise and, to manual or automated test methodologies requiring little technical expertise and no problem-solving, interpretative ability. Personnel would be required to demonstrate competency in performing each offered test, and demonstrated performance of appropriate quality control measures would be required for each test and instrument. Moreover, every lab would have to engage in four annual proficiency tests for each methodology and instrument offered. Level One labs would be required to have an individual such as a certified medical technologist as a consultant to provide instruction, review of quality assurance, and assistance in review and interpretation of abnormal test results.

Laboratories would be categorized according to the highest level of methodology it employs. Thus, if a Level One lab begins to offer a test that is categorized as a Level Two methodology, the laboratory would then be required to follow the personnel standards for Level Two. However, ASMT envisions that the majority of tests performed in POLs would fall under Level One.

Level Two labs would include methods that are either more technically demanding or require some interpretive and independent judgment. Level Three labs would include sophisticated methods requiring a high degree of technical expertise and independent judgment. Quality control measures and proficiency testing requirements in levels two and three would be identical as those in level one. Personnel standards in level two labs would require at least a certified medical laboratory technician; in level three, it would require at least a certified medical technologist.

We propose that the federal Drug Administration (FDA) enforce its statutory power to assess laboratory equipment/technology and restrict the performance of certain laboratory equipment/technology based upon its complexity and/or quality. Support for this approach is found in the legislative history of the 1976 Medical Device Amendments of the Food, Drug, and Cosmetic Act. Not only do the amendments categorize devices, including diagnostic test kits and equipment into three classifications, but they also empower the Food and Drug Administration to issue device approvals with restrictions. The Cooper Commission, which recommended the device amendments, expressed concern about the hazards that were the result of the way medical devices were used. They suggested that restrictions or limitations be placed on the sale or distribution of devices to particular categories of health care professionals. Thus the amendments authorized the FDA to restrict a type of device by regulation [section 520 (e) (1)], to include a restriction as a part of a mandatory performance standard for a class II device [section 514 (a)(2)(B)(v)], or to include a restriction as a condition to its approval of a premarket application for a class III device [section 515 (d)(B)(ii)].

The FDA's ability to restrict the use of a laboratory device can serve as an important element in the new regulatory approach. The FDA approval process not only could place a new laboratory device into Class I, II, or III FDA classification, but also could limit or restrict its use to certain regulatory levels. A highly automated and internally calibrated device might be placed under Level One, with minimal restrictions, while a technically complex instrument would be placed under Level Three, with quality control appropriate for the technology and with more stringent personnel standards due to the interpretive ability needed for performance of the test.

The FDA has jurisdiction over devices released since 1976. We suggest that the FDA expert panels review laboratory devices approved since that time and recommend appropriate restrictions to prevent the misuse of the devices by practitioners. These restrictions would parallel the regulatory requirements of the several method-specific classification levels. This again follows a recommendation of the Cooper Commission to establish conditions under which devices cold be used or qualifications for those who use them (4). For devices or methods not under FDA jurisdiction, we recommend that a broad based laboratory consensus panel be established within a currently existing agency or organization (e.g., NCCLS or CDC) to determine the appropriate method-specific classification level.

In conclusion, it is interesting to note that we are not the only country that is dealing with the issue of laboratory quality, even with a technology that is designed to require little operator expertise -- blood glucose monitoring devices. Following an unfortunate occurrence in Great Britain last fall, the British Department of Health and Human Services was forced to issue a Hazard Notice on October 15 --

> The use of ~~blood~~ glucose by untrained staff, without adequate management supervision of the equipment and without the use of quality control procedures, can lead to misleading results, adversely affecting the treatment of patients. Those unfamiliar with equipment should be forbidden to operate it unless supervised or until they are competent in its use.

Given the varying locations for test performance, the diversity in the complexity of the technology and methods, and the range of skills of the personnel currently performing the testing, our challenge is how to assure high quality laboratory services while respecting diversity when appropriate, but standardizing regulations when necessary. We believe that our model is a response to that challenge and is targeted at the roots of the problem -- the quality of the technology and the appropriate personnel to perform and supervise the tests. Of course further study, research, and demonstration projects will be necessary, but we believe that the ASMT model is a first step in reforming our 23 year old regulatory approaches in light of the present range of technology and diversity of performance sites.

ASMT

REGION VI

Illinois
Iowa
Kansas
Missouri
Nebraska

VI G.

NEBRASKA SOCIETY FOR MEDICAL TECHNOLOGY
External Quality Control
1987 Summary Report

I. Participant Recruitment

A. Initial Contact

In November 1986, letters were sent to 726 primary care physicians in Nebraska. These specialities included family practice, internal medicine, obstetrician-gynecologists and pediatricians. The letter included a return postcard for response.

B. Query Cards

From the initial mailing of 726 letters, 48 (7%) query cards were returned showing interest in more information. This included educational programs and/or quality control.

C. Initial Enrollment

The 48 query cards were answered with letters for enrollment. The program was explained more completely and the enrollment fee was to accompany any response. Final enrollment was 17 offices (35% of B or 2% of A) geographically located throughout the state. Fifteen offices were family practice; two were internal medicine.

II. Referees

Six Omaha area hospitals or reference laboratories were used as the referees. All are certified by either JCHO or CAP.

III. Program

A. Frequency

Materials were to be sent quarterly with two mailings in chemistry and two in hematology/urinalysis.

B. Constituents

Chemistry constituents evaluated were glucose, potassium, uric acid, cholesterol, and total bilirubin.

Hematology constituents evaluated were red cell count, white cell count, hemoglobin and hematocrit.

Urinalysis constituents evaluated were the chemical pad tests only, including pH, protein, glucose, ketone, occult blood, bilirubin, urobilinogen, specific gravity, nitrites and leukocyte esterase.

C. Materials

Chemistry material was Fisher SeraChem unassayed chemistry control. Level I was sent the first quarter and Level II was sent the third quarter. Compiled data summary sheets supplied by Fisher were used for the target ranges.

Hematology material was supplied by Streck Laboratories. The Para 4 material had assigned assayed values that were used as target ranges. The second quarter specimen was in the normal range and the fourth quarter specimen was in the high abnormal range.

Urinalysis material was EM Diagnostic Systems Urintrol in the second quarter. The fourth quarter material was ICL Scientific's Kovatrol III, the normal/negative range. Both materials had assayed values that were used for the target ranges.

IV. Distribution

All materials were sent using United Parcel Service. Enclosed with the material was specimen handling information and a reporting form. Participant and referee material was packaged and shipped identically.

V. Results

A. Participants

A break down of participant results is as follows:

CHEMISTRY

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
Glucose	29	14	48
Potassium	21	9	43
Uric Acid	21	15	71
Cholesterol	24	15	63
Bilirubin	16	8	50
Totals	111	61	55

HEMATOLOGY

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
RBC	10	2	20
WBC	22	12	55
Hemoglobin	28	17	61
Hematocrit	25	9	36
Totals	85	40	47

URINALYSIS

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
pH	29	5	17
Protein	29	0	0
Glucose	29	4	14
Ketone	29	0	0
Occult Blood	29	10	34
Bilirubin	29	1	3
Urobilinogen	29	2	7
Specific Gravity	25	3	12
Leukocte Esterase	21	1	5
Nitrite	24	0	0
Totals	273	26	10

B. Referees

A breakdown of referee results is as follows:

CHEMISTRY

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
Glucose	11	1	9
Potassium	11	1	9
Uric Acid	11	2	18
Cholesterol	11	1	9
Bilirubin	11	2	18
Totals	55	7	13

HEMATOLOGY

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
RBC	15	2	13
WBC	15	0	0
Hemoglobin	15	8 *	53
Hematocrit	15	7 *	47
Totals	60	17	28

* All results by referees were outside acceptable limits on a single specimen. This probably was due to the material and/or instrument rather than a technical assay problem.

URINALYSIS

Constituent	Total Assayed	Results > 2 SD	%Outside Acceptable Range
pH	13	1	8
Protein	13	0	0
Glucose	13	1	8
Ketone	13	0	0
Occult Blood	13	1	8
Bilirubin	13	1	8
Urobilinogen	11	0	0
Specific Gravity	13	0	0
Leukocyte Esterase	8	0	0
Nitrite	7	0	0
Totals	117	4	3

VI. Methods and Instrumentation

A. Participants

A list of instruments and methods used for the testing is:

Chemistry:
Ames Serolyger
ENI Gemotar
Gilford System 103
BM Unimeter
BM Reflotion
Abbott Vision
Kodak DT60
Nova I
AVL 982
BM - BioLytetek

Hematology:
Unopette and Hemacytometer
Coulter M430
Bio-Dyn CellTrak 3
TOA CC-110
Danam SA-1000
AmesSerolyzer
Abbott Vision
BM - Reflotron
Kodak DT60
Spun hematocrit

Urinalysis:
Ames N-Multistix - SG
Bio-Dynamics Chem 9, Chem 6L

B. Referees

A list of instruments and methods used for the testing is:

Chemistry: Kodak Etkachem 700
Beckman Astra 8
Technicon SMAC II
Hitachi 705
Technicon SMA II
DuPont ACA
IL 508

Hematology: Coulter S+IV
TOA cc800
Coulter T660
Coulter S+II
Ortho ELT-8

Urinalysis: Ames Clinitek with N-Multistix-SG
Bio-Dynamics Chem 9
Ames N-Multistix-SG .

VII. Follow Up

A. Reports

Result reports were sent to all participants and referees. Reports included their assayed value, the target range and whether the reported value fell within acceptable limits.

B. Educational Material

Inserted with all participant results was an educational topic for information. Topics covered were 1) basic quality control; 2) proper specimen collection and handling; 3) variables in specimen processing including equipment, reagents, methods, standards and controls, and personnel; and 4) result evaluation and reporting. Educational material was not sent to referee laboratories.

The Nebraska Society for
Medical Technology, Inc.

November 19, 1986

TO: Physician's Office

FROM: Deb Hassler, MS, MT(ASCP) Deb Hassler
Nebraska Society of Medical Technology

RE: External Quality Assurance Program

Your office returned an inquiry card to NSMT in regards to the external quality assurance program sponsored by the society. The response to our initial mailing was very good. We are pleased that there are many quality conscience offices such as your own.

This program will help your laboratory personnel become familiar with a proficiency testing program and its benefits. It is designed for offices doing limited testing and does not meet the standards for a Medicare approved proficiency testing program.

Specimens will be sent quarterly, with two quarters being chemistry constituents and two quarters being hematology and urinalysis. Included will be complete instructions for preparation and submission of results.

The report returned to you will give your result and the expected target range for your method as determined by the specimen manufacturer. It will not be forwarded to any third parties.

The fee for this program is $50.00. Sign up deadline is December 20, 1986. Please complete the attached form and return as soon as possible. The first specimen will be sent in January, 1987.

DH/ss

Enclosure

Please enroll me in the NSMT External Quality Assurance Program.

Enclosed is my enrollment fee of $50.00. (Make checks payable to Nebraska Society for Medical Technology.)

Please send result reports to:

Clinic Name: ____

Attention: ____

Address: ____

City: ______________________________ State: __________ Zip: ______

Phone Number: (____) ____

Thank you.

MAIL TO: Deborah Hassler, MS, MT(ASCP)
9620 Sprague
Omaha, NE 68134

The Nebraska Society for
Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

Instructions:

1. This package contains two (2) vials. Upon arrival, check for broken or leaking vials. Refrigerate until testing can be performed. The vials should not be left at room temperature for more than 30 minutes.
2. Specimen 4H: Allow sample to stand at room temperature for approximately 15 minutes. To mix, roll the vial gently between the palms of the hands (varying vial position from vertical to horizontal) for at least 10 seconds; invert vial and repeat. DO NOT MIX MECHANICALLY. After mixing, use the sample in the same manner as a fresh whole blood specimen.
3. Perform the tests listed which are normally done in your laboratory.
4. Be sure to indicate if TEST NOT PERFORMED in your laboratory.
5. Specimen 4U: Remove the seal from the bottle. Slowly remove the rubber stopper to prevent escape of the dried material as the vacuum is broken. Add exactly 10 ml of distilled or deionized water to vial. Immediately replace the rubber stopper in the bottle and gently rotate the bottle intermittently until all of the material has disolved (approximately 20 to 30 minutes). After reconstitution, the material may be used up to five days if kept at 2-8°C. Allow to reach room temperature prior to testing.
6. Perform the tests listed which are normally done in your laboratory. Timing for test strips must be followed exactly to achieve reliable test results.
7. Be sure to indicate if TEST NOT PERFORMED in your laboratory.
8. Complete the enclosed page and return within 15 working days after receiving specimens to:

   Deborah Hassler, MS, MT(ASCP)
   9620 Sprague Street
   Omaha, NE 68134

   Date package received ______________________________

9. It is recommended that you photocopy the result form for your files.

DH/ss

The Nebraska Society for Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

Clinic Name ______________________________

Address ______________________________

____

Date ____________________

	Instrument	Specimen 4H Result		Test Not Performed (check one)
RBC count	________	________	x 10^{12}/L	☐
WBC count	________	________	x 10^{9}/L	☐
Hemoglobin	________	________	%	☐
Hematocrit	________	________	gm/dl	☐

	Test Strips/Method	Specimen 4U Result	
pH	________	________	☐
Protein	________	________	☐
Glucose	________	________	☐
Ketone	________	________	☐
Occult Blood	________	________	☐
Bilirubin	________	________	☐
Urobilinogen	________	________	☐
Specific Gravity	________	________	☐
Leukocytes	________	________	☐
Nitrite	________	________	☐

Return to: Deborah Hassler, MS, MT(ASCP), 9620 Sprague, Omaha, NE 68134

The Nebraska Society for Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

April, 1987 Sample

Clinic:

Component	Result	Acceptability	Acceptable Range
RED BLOOD COUNT (RBC)	$X10^{12}/L$		
WHITE BLOOD COUNT (WBC)	$X10^{9}/L$		
HEMOGLOBIN	gm/dl		
HEMATOCRIT	%		
pH			
PROTEIN			
GLUCOSE			
KETONE			
OCCULT BLOOD			
BILIRUBIN			
UROBILINOGEN			
SPECIFIC GRAVITY			
LEUKOCYTES			
NITRITE			

The Nebraska Society for Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

Instructions:

1. This package contains one (1) vial. Store vial in refrigerator.
2. When ready to test, remove the metal seal and rubber stopper.
3. Add exactly 10 ml of distilled or deionized water to the vial. Volumetric pipets will be more accurate.
4. Replace the stopper, swirl gently to mix, and allow 10-15 minutes for complete reconstitution. Avoid excessive shaking.
5. Mix thoroughly again before removing aliquot for assay.
6. After reconstitution, the material may be used for up to five days if kept at 2-8^{0}C, except that all assays for total bilirubin should be performed within 48 hours.
7. Perform the tests listed which are normally done in your laboratory.
8. Be sure to indicate if Test Not Performed in your laboratory.
9. Complete the enclosed page and return within 15 working days after receiving specimens to:

   Deborah Hassler, MS MT(ASCP)
   9620 Sprague Street
   Omaha, NE 68134

   Date package received ____________________

10. It is recommended that you photocopy the result form for your files.

DH:nd/ss
12/11/86

The Nebraska Society for Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

Clinic Name ____________________

Address ____________________

____

Midwest

Date ____________________

	Instrument/Kit	Result	Test Not Performed (Check Box)
Glucose	________	______ mg/dl	☐
Potassium	________	______ mmol/L	☐
Uric Acid	________	______ mg/dl	☐
Cholesterol	________	______ mg/dl	☐
Bilirubin	________	______ mg/dl	☐

Return to:

Deborah Hassler, MS MT(ASCP)
9620 Sprague Street
Omaha, NE 68134

The Nebraska Society for
Medical Technology, Inc.

EXTERNAL QUALITY ASSURANCE PROGRAM

July , 1987 Sample

Component	Result	Acceptability	Acceptable Range
Glucose			
Potassium			
Uric Acid			
Cholesterol			
Bilirubin			

American Society for Medical Technology
2021 L Street, N.W.
Suite 400
Washington, DC 20036
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ASMT WHITE PAPER

INDEPENDENT PRACTICE IN CLINICAL LABORATORY SCIENCE

May 1987

THE ISSUE: SHOULD THE AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY (ASMT) ASSERT AS A LEGITIMATE COMPONENT OF THE SCOPE OF PRACTICE OF THE CLINICAL LABORATORY SCIENTIST HIS OR HER RIGHT AND QUALIFICATIONS TO ESTABLISH INDEPENDENT PRACTICE IN CLINICAL LABORATORY SCIENCE?

Background: The issue of independent practice for various allied health professions has received and continues to receive serious attention from health policy analysts, practitioners, educators, private credentialing entities, federal and state regulatory and legislative bodies, third party payors, providers, and other employers of allied health professionals.

Though not a new subject, the issue has acquired a new immediacy due to sweeping, systemic changes in the organization, delivery and payment of health services in an environment characterized by: (a) a crisis in healthcare cost containment; (b) problems of patient/consumer access to competent care; (c) unresolved debate within and among allied health and medical professions over traditional scopes-of-practice and closely-related professional educational, licensure and credentialing needs and practices; and (d) the unique ability of specific allied health practitioners to provide more appropriate care, and thus care superior to that provided by any other practitioner.

With the recent call for a 1987 Critical Issues Conference entitled, "Independent Practice?: What is the Appropriate Level of Autonomy for Health Care Practitioners?," the importance of the issue for allied health professionals was once again emphasized.

Relationship to Existing Societal Positions: In previous statements of opinion, policy and position, the American Society for Medical Technology (ASMT) has established that clinical laboratory science is a profession: (a) distinct from the practice of medicine; (b) characterized by its own, internally-defined Body of Knowledge and Scope of Practice; and (c) requiring of its practitioners competency in scientific, technical, managerial and scholarly principles, and high standards of achievement and professional conduct. Further, ASMT has historically asserted that duly-qualified practitioners of clinical laboratory science have the right to practice their discipline to the fullest extent of their competence, without unnecessary and unfair constraint.

ASMT defines the profession as encompassing the performance, reporting, interpretation and clinical correlation of clinical laboratory tests for the purpose of promoting health and preventing and treating disease and impairment through the application of scientific principles of biology, chemistry and physics as they relate to physiologic and biochemical processes in the human being. The clinical laboratory science profession also incorporates principles of social science to serve its primary purpose. The profession includes generalists as well as individuals qualified in a number of specialized areas of competence, and includes as integral features, research, consultation, education, management and administration.

In a document currently under review by the ASMT House of Delegates, the Society proposes to establish as its mission: "to improve the public health through promotion of efficient and effective use of health care resources relative to clinical laboratories by: (1) espousing public and professional policies necessary for an adequate supply of competent practitioners; (2) promoting practice at a level commensurate with the expertise of the profession and by removing artificial barriers to such practice; and (3) explaining the role of laboratory personnel to the public."

In accord with established positions and policies, and with the proposed mission statement and the proposed 1987 Strategic Planning Document of the ASMT, the Society has undertaken consideration of the prospects for and feasibility of forms of independent practice for the qualified clinical laboratory scientist.

Statement: First, it should be noted that non-physician clinical laboratory scientists already function -- and will do so increasingly -- as independent practitioners, in their capacities as directors of full-service clinical laboratories. The competence of, and right of, non-physician clinical laboratory scientists to direct full-service clinical laboratories are firmly ensconced in (a) applicable state law, (b) regulations governing hospital and independent laboratory participation in Medicare and Medicaid, and (c) regulations governing interstate clinical laboratories promulgated under the Clinical Laboratory Improvement Act of 1967. These laws and regulations permit non-physician clinical laboratory professionals to direct full-service clinical laboratories in all settings, and thereby to exercise autonomous decision-making within the scope of their professional practice. While certain facility accreditation standards promulgated by private-sector, physician-controlled entities such as the Joint Commission on the Accreditation of Hospitals (JCAH) and the College of American Pathologists (CAP), have imposed or sought to impose their preferences for physician directors as a condition for facility accreditation, (1) in most instances, these standards are under serious review toward eliminating such preferences, and (2) in any event, they constitute arbitrary barriers and do not vitiate the reality that non-physicians may, and do, serve in this capacity as independent practitioners.

Second, the Society recognizes that the profession is challenged to assume expanded roles and responsibilities by sweeping technological innovations, cost-containment imperatives, radical revisions in service delivery sites and methods, and other important environmental forces (e.g., threats to the assurance of quality of care; inequitable patient/consumer access to affordable, quality services; federal drug abuse prevention initiatives; and disease-state crises threatening the public health).

Indeed, the Society observes that these momentous changes have already established actual practice requirements as a significant force in determining scopes-of-practice for health professionals. These changes, for instance, have often outpaced educational program accreditation requirements (and related certification requirements) and have, in fact, often compelled providers and practitioners (and even payors) to press accrediting bodies, certification entities, and state and federal regulators, to modify their respective requirements to conform to new practice patterns.

In short, the Society perceives a significant inversion of the traditional roles of the (a) practice setting and practitioner, versus (b) accrediting, certification, licensure and regulatory entities, in determining clinical laboratory qualifications and domains, in particular.

This inversion has had several important consequences. Principally, technological changes, cost containment pressures and increased competition, have enabled individual practitioners who, by education and experience are at the forefront of their profession, to develop previously incipient competencies into fledgling career paths in advance of revised education program essentials and certification mechanisms. In clinical laboratory science, for example, such practitioners have transformed previously informal (but firmly established) functions, such as consulting with attending physicians on test selection and sequencing, interpretation, and clinical correlation, and laboratory management and administration, into emergent new career paths in clinical laboratory utilization management, and laboratory-based and entrepreneurial laboratory management consultancy.

Such developments are fully consistent with the Society's position that clinical laboratory scientists should be free within their legitimate scope of practice to make autonomous decisions about clinical laboratory practice issues independent of practitioners who are not members of their profession. These developments also serve to underscore the legitimacy of that position in actual practice.

However, because these developments have overtaken collateral curricular, certification, licensure and other personnel regulatory modifications, these career paths, which are among feasible spheres of independent practice, should be viewed as both inherent in the clinical laboratory scientist's traditional scope of competency and yet, also still in their formative stages. In ASMT's assessment, this means that public personnel regulatory mechanisms must speedily provide the regulatory adjustments necessary in order for the qualified clinical laboratory scientist to achieve bona fide practice in these spheres.

Just as the Society recognizes and affirms the profession's proactive response to the myriad environmental forces that have called forth responsible visions of competent, qualified forms of independent practice, the Society also recognizes and affirms the profession's distinctive collegial relationship to the medical profession, whose practitioners, alone, perform medical diagnosis and authorize diagnostic and clinical treatment protocols. Affirming that distinctive collegial relationship, and affirming the right, responsibility and qualifications of clinical laboratory scientists to meet contemporary health service delivery challenges, ASMT envisions several forms of autonomous, independent practice for appropriately-qualified clinical laboratory scientists. These are:

A. Directors of Full-Service Clinical Laboratories: As already noted, this independent practice role is a reality which requires only the removal of arbitrary barriers imposed by the private sector in order to become normative.

B. Consultants for Clinical Laboratory Services: Clinical laboratory scientists may appropriately provide technical assistance to physicians, manufacturers, and end-users of clinical laboratory services, including: advising upon the design and service scope of clinical laboratories; advising physicians in the appropriate utilization, selection and sequencing of clinical laboratory tests and, in collaboration with attending physicians, determining clinical correlations and interpretations of the quality and utility of specific laboratory results; advising manufacturers upon the design and development of clinical laboratory instruments, test kits and other components; and advising other users and consumers of clinical laboratory services upon appropriate use, maintenance, quality assurance and other procedural and informational requirements.

C. Providers of Clinical Laboratory Services Upon Either Physician or Consumer Request, in Facilities Owned or Operated by Clinical Laboratory Scientists: Within the scope of practice governing the profession, and consistent with ethical and legal considerations, clinical laboratory scientists qualified by education and experience should be able to perform tests and provide results to consumers upon request or upon physician referral, in laboratories which clinical laboratory scientists own or operate. In all such cases, clinical laboratory scientists are obliged to exercise prudence and judgment to ensure that such services are consistent with good practice and sound professional ethics.

D. Providers of Disease-State Risk and Wellness Assessments: Clinical laboratory science is and remains distinct from the practice of medicine, which renders diagnosis and provides treatment for human beings. While clinical laboratory scientists provide critical information, they do not diagnose or prescribe treatment under any conditions, and therefore they may qualify by education and experience to perform test screens to identify the presence or absence of factors known to be associated with risk of disease or or impairment. Such services may include but are not limited to performing and reporting to consumers the results of tests to determine, e.g., blood cholesterol levels, and e.g., the presence or absence of metabolized substances of abuse. In all such cases, clinical laboratory scientists are bound by applicable law and regulation, as well as by standards of good practice and sound professional ethics, in their relationships with consumers and with practitioners of medicine.

Finally, ASMT wishes to emphasize that the independent practice roles envisioned for the clinical laboratory scientist differ to some extent from traditional interpretations of independent practice, which tend to assume a direct patient-care relationship that involves, in varying degrees, the provision of treatment services. The roles envisioned here require neither revision of the scope of practice of clinical laboratory science, nor revision of the scope of practice of practitioners of medicine, though they may involve removal of artificial barriers to the qualified provision of cost-effective, high-quality clinical laboratory services by non-physician professionals. Primarily, however, the roles envisioned here assume: (a) collegial relationships between non-physician clinical laboratory scientists and physicians, in clinical utilization and correlation issues, and (b) the provision of these services and of information relative to risk assessment, wellness, the determination of the use/abuse of substances, and consumer or physician requested testing and results, consistent with good practice standards, consumer confidentiality and civil protections, applicable law and regulation, the Scope of Practice of the Profession, and sound professional ethics.

ASMT's White Paper on Independent Practice in Clinical Laboratory Science is intended to contribute to the debate concerning appropriate levels of autonomy for allied health professionals, and is subject to further study and revision.

MCG

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SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
UNITED STATES SENATE
March 23, 1988

Paul Fischer, M.D.

For the past seven years I have served as an "office laboratory director," first in solo practice in Weeping Water, Nebraska, and then at the Family Practice Center at the Medical College of Georgia. When I first used this term "office laboratory director" some individuals in the laboratory community thought it strange since they did not believe that office laboratories were "real" laboratories. Clinicians had a similar quizzical response. They said, "I don't have an office laboratory, I just do a little testing." What I would like to do for the next few minutes is to describe the office laboratory environment from a clinician's perspective. Unlike many people who have an opinion on this subject, I spend time everyday in an office lab.

WHY DO PHYSICIANS DO OFFICE TESTING?

A variety of reasons have been cited as explanations for why physicians do office testing. I believe that the clinician's overriding concern is to provide high quality and efficiently managed patient care.

Let me give you a quick example of how office testing can improve patient care. Suppose that you came to my office five years ago and had problems with asthma. Theophylline is one of the common medications to treat this illness. A "serum theophylline level" is used to monitor the drug dosage to be sure that enough drug is being prescribed but not too much so as to cause patient harm. If you came into my office five years ago and were on theophylline and had wheezing I would have drawn a theophylline level and sent it off to an outside reference laboratory. I would have been hesitant to increase the drug dosage since this could lead to toxic side effects. If we were lucky, the blood would have been picked up by the reference laboratory on time, tested appropriately, and the results mailed back to my office. Three or four days after your visit, I would have called you up to tell you that the test had indicated that your drug level was low and that you needed to be on a higher dose of theophylline. You would wheeze in agreement and complain about the test delay. The testing process and its associated inconvenience, would have been frustrating for you and for me.

If the same patient came to my office today, I would do a theophylline test and have the results are available in 20 minutes. The dosage can be adjusted immediately if indicated. This rapid office testing provides better care to the patient and saves my spending time following up the laboratory result two to three days after the patient's visit. The average time for a physician to follow up a laboratory test has been estimated to be 14 minutes. This includes reviewing the result, contacting the patient, calling the pharmacy and writing a new note. It is easy to see how office testing can improve the efficiency of patient care and therefore, why physicians are interested in its development.

HOW GOOD IS OFFICE TESTING?

We unfortunately have very little direct data to answer this question. This is in large part because there has been almost no funding of research in this area. The only direct data come from the proficiency testing programs which are organized by professional organizations, diagnostic industry manufacturers, and a few state health departments. The published data from the ASIM and CAP proficiency testing programs indicate that the testing in participating office laboratories is actually very good and in most cases is comparable to the testing in hospital and reference laboratories. Unfortunately , the total number of laboratories which participate in these various PT programs is less than 10,000. This represents only about 10% of all office laboratories and it is likely that these laboratories are not representative of the other 90,000 laboratories. A laboratory which voluntarily participates in PT is usually a very good lab. PT is the principle way that laboratories assure the external validity of their results. The fact that most office laboratories do not participate in a PT program, is therefore indirect evidence, in my opinion, that there may be a problem with office testing.

There are two other types of indirect evidence. The first of these is the fact that most office testing is done by people without formal laboratory training. These include nurses, medical assistants, and receptionists. Most surveys of office laboratories have indicated that about 30% of laboratories have formally trained personnel. In a study which we did in Georgia in cooperation with the CDC, we asked for the credentials of everyone in the office who did testing. When these data were analyzed, it appeared that only about 10% of all persons doing some testing, were formally trained in laboratory methods. It is likely that the informal training of the remaining 90% is quite variable.

The final piece of indirect evidence, is the fact that there are almost no educational programs available to teach clinicians or their staff about what is needed to produce good laboratory testing. In a national study that we conducted in family medicine residency programs, only 15% of residency programs had any formal training in laboratory management. Despite this low percentage, family medicine has been more attentive to the laboratory training needs of their residents than any other clinical discipline.

HOW EFFECTIVE ARE STATE REGULATIONS?

While 14 states currently have adopted some regulation of office laboratories, it should be recognized that these regulations have had only a limited impact. These regulations are often written to exclude most of the real office laboratories. The administrative resources which are allocated are usually very limited. The regulations often lack effective penalties. They are to a large extent regulations of convenience. This has been necessary because office laboratory regulation (in the usual sense of the word) is a huge and complex task. Those states which have had the biggest impact on office lab test quality are probably Idaho and Pennsylvania. In these two state programs the regulatory staff have principally taken on an educational rather than a regulatory role.

WHAT ARE THE COMPONENTS OF AN IDEAL PROGRAM FOR OFFICE LABORATORIES?

Thirty years ago, hospital and reference laboratories had major problems with the quality of their testing. A variety of regulatory mechanisms were therefore instituted. The *principles* of these mechanisms are appropriate for an office laboratory program but it should be emphasized that the *details* are likely to be very different. An office laboratory is not just a small hospital lab!

1. Education. Most physicians want to provide good patient care and therefore want to do good testing in their laboratory. However, to a large extent, the current training of physicians does not provide the skills necessary to direct a laboratory nor to even recognize when poor testing is being done. Clinician education must therefore be the center for any office laboratory program.

2. Personnel. Rigid personnel standards are an impractical solution. It *is* appropriate for nurses and medical assistants to do some types of testing in the office laboratory. Technology now exists which permits reliable testing by people without years of laboratory training. This same technology permits any woman in America to buy a pregnancy kit from her pharmacy and to diagnose her own pregnancy, in the privacy of her "bathroom laboratory," even before she has missed a period. If the technology is good enough for the public, it is certainly suited

for the nurse working under the supervision of a physician in an office laboratory.

3. Proficiency Testing. Proficiency testing permits the clinician to compare the office laboratory's results with that of other similar laboratories. It has only been very recent that a proficiency testing program suitable for office laboratories has existed. Required proficiency testing and suitable performance on this testing are probably the most important components to any proposed office laboratory program.

4. On-site Inspection. It would obviously be impossible to regularly inspect 100,000 office laboratories. In addition to being impossible, it is also unnecessary. An ideal program should identify laboratories which have problems and focus the expensive resource of on-site inspection on those laboratories. Above all else, inspection is an educational intervention.

5. Quality Control. Quality control procedures are those things which a laboratory does every day to be sure that its testing is good. The specific recommendations for "good quality control," as it is now practiced in hospital and reference laboratories, is to a large extent, dogma, reinforced by habit, and has little to do with the stability of today's test systems. Many hospital and reference laboratories practice overkill in quality control. More is not necessarily better. Enough is enough. Any recommendations for quality control in an office laboratory program should be based on the stability of the test, the qualifications of the intended user, and the clinical context in which the test data will be used. The latter is often of little concern to hospital and reference laboratories. It is however, at the heart of the clinician's concerns. The principles of quality control in an office laboratory program will be the same as those for any other laboratory, however, the details should in some cases be quite different.

WHAT IS THE GOVERNMENT'S ROLE IN REGULATING OFFICE LABORATORIES?

We are at the beginning of an evolutionary process which will take three to five years and will lead to a marked improvement in the quality of office testing. There are no inherent reasons why testing in a physician's office should not be as good as laboratory testing at any other site. To support these evolutionary changes, I believe that the federal government should:

First, fund research which examines the quality of office testing. The government is responsible for developing regulations when there is a public health risk. At this point in time, there are too few data to know the risk from office testing. One would be establishing policy in a vacuum without knowing more about the problems that now exist.

Second, fund the development of demonstration projects aimed at improving office laboratory testing. Support for a project like COLA would be a good first step.

Finally, the best regulation is "threatened regulation." Threatened regulation will likely serve as an impetus to the diagnostic industry, to clinicians, to professional societies, and to state governments to resolve the problems associated with office laboratory testing. If after a reasonable period of time, this evolution in office laboratories has not occurred, it would be in the public's best interest to establish a federal regulatory system. By that time, there should be more information, so that it would be clearer how to put together an effective and reasonable regulatory program.

The changes in technology and the restructuring of health care delivery have both contributed to the decentralization of laboratory testing. Your home bathroom laboratory can now do tests that were not even possible for hospital laboratories to do just ten years ago. This process will continue and it can be managed.

TESTIMONY FOR THE SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT

PRESENTED BY
VIRGINIA L. WORREST, CLS (NCAMLP)
MARCH 23, 1988

In 1986, the State of Oregon Public Health Laboratory and the Oregon Health Sciences University (OHSU) received a grant from the Centers for Disease Control (CDC) in Atlanta, Georgia, the objective being to determine whether educational material supplied to physician office laboratory personnel is a feasible means for effecting improvements in the performance of microbiology laboratory testing by physician office laboratories. Additionally, this study was intended to provide demographic information regarding physician office laboratories in Oregon: the scope of testing in these facilities and how the testing is being done and by whom. Other states awarded CDC study grants were Georgia, North Dakota and West Virginia.

The study involved 40 unlicensed and 20 licensed physician office laboratories (POLs) selected to reflect the mix of POLs in the State. These laboratories first were asked to identify unknown microorganisms sent as part of a microbiology proficiency testing program. The POLs were then surveyed by a qualified medical technologist to obtain demographic data regarding the scope and nature of testing done in these settings. After this external and internal audit of laboratory performance, educational materials, consisting of a microbiology instructional handbook and accompanying slides, were supplied to each of the participating laboratories. After sufficient time for usage, the laboratories were again evaluated via a proficiency testing program, a written cognitive test and a second site survey. After a period of time, a third survey was conducted where contamination of survey results was no longer a concern and the participants were requested to seek the expertise of the surveyors. Of great significance to the following information is the fact that all 40 unlicensed laboratories surveyed had VOLUNTEERED for the survey. The 20 licensed laboratories selected for the survey undergo routine, annual state inspections in order to receive state licensure.

For purposes of understanding the information given in this testimony, it should be noted that recent advances in laboratory technology have made available an array of analytical systems that can provide physicians with the ability to analyze numerous patient specimens in their office laboratories. This "black box" technology occurs when the operator merely pushes a button and results are usually read or interpreted directly from the analytic system. There is, however, a wide-spread belief that the variability of test results produced in this setting is significantly greater than that found in hospital or commercial laboratories. Evidence from several studies indicates that the greater variability of results from office laboratories may be due to the lower education and experience levels of office laboratory personnel. It has also been noted that the expertise of the operator is a major factor in the quality of the results and that, when manufacturer's instructions have not been followed, clinically significant errors have occurred.

In carrying out my surveys at 12 physician office laboratory sites, I found:

1. a definite lack of adherence to the quality assurance guidelines that are designed to insure the proper functioning of instruments and equipment,
2. a lack of understanding of quality control concepts,
3. the inappropriate use of quality control protocols to validate the reliability of the analytical systems on a day-to-day basis.

Quality control (QC) is a series of regularly followed procedures that assure a certain level of accuracy to a test result. Physicians and nurses who supervise POL testing often find their responsibilities for laboratory testing only incidental to the major focus of their responsibilities, that of direct patient care activities. Employing a person trained for the level of testing carried out in any given physician office laboratory is certainly a feasible means for effecting improvements in performance of laboratory testing and providing health care in an effective manner at a reasonable cost.

The most common problem seen in doctors' offices is an upper respiratory infection. It has been stated that 15,300,000 visits are made to the physician each year at a treatment cost of $3000 million. It has been estimated that a child will experience 10 such infections per year and every adult, 3 to 4. In many of these patients, a sore throat is the primary symptom.

The most reliable method for diagnosing a Group A hemolytic streptococcal infection (known as a "strep throat," and for causing, among other diseases, rheumatic fever) is a throat culture. Diagnosis only by symptoms is unreliable. Correct specimen collection for a strep culture is critical, as is the proper incubation of the culture and the correct interpretation of the culture plate, so as to provide an accurate diagnosis of the causative microorganism. The interpretation of a throat-culture-plate is sometimes tricky and requires knowledge of hemolysis patterns, disc inhibition, and colony morphology. In carrying out my surveys, the accurate interpretation of the throat culture was found to be the single hardest task for the people doing the laboratory work. In my twelve POLs surveyed, approximately 40 doctors, nurses, receptionists and other on-the-job trained personnel conducted these tests. Only two were qualified medical technologists. It must be remembered, also, that the throat culture is the only technique that can easily identify those patients with sore throats who are NOT infected with the Group A streptococci and who, therefore, can be spared the costs, risks, and the inconvenience of antibiotic therapy. Recently on the POL scene are kits for rapid diagnosis of strep throats, among other disease states, which untrained personnel find easier to interpret. However, parallel tests have shown that the kits are not as accurate as an actual throat culture and thus are not the answer to the problem of misdiagnosis. Most kits currently in use do not include proper verification techniques thus leaving the lab personnel with no simple way to check an analytic system's day-to-day reliability.

CASE PROBLEM #1

I observed a case where a doctor transported his incubator between his country home office and town office, electrically plugging it in when needed for a strep culture. No temperature check was made even though the streptococcus grows at an optimum of 35-37°C, with the possibility of unsatisfactory growth at a few degrees above or below this, which can yield results interpreted as negative. Also, the doctor asked me to convey to the State Laboratory the fact that the 'unknowns' received from the State Laboratory (microorganism samples to be tested and diagnosed and answers sent back to the Laboratory for determination of accuracy) did not grow and that "there must be something wrong with the specimens they sent." Shortly after this comment, I overheard the doctor in the next room with a returning patient, a small boy who still had his sore throat. The boy was told that it must be a virus because his throat culture was "negative" and no antibiotics were needed for treatment. It was only in discussion with the physician immediately following, when I mentioned the inaccurate incubation of throat cultures, that the doctor truly realized the possibility of a misdiagnosis. I have wondered many times since this experience if that little boy actually had a strep throat and, if so, would it have gone on to cause a disease as severe as rheumatic fever, incapacitating him for a long time, not to mention prophylactic antibiotic treatment for the rest of his life, and changing the quality and possibly affecting the longevity of his life. And what of the emotional burden to his family and the financial burden to his insurance company, if he had insurance, and to the entire health care system? My observation was that this doctor was an intelligent, very caring doctor working for an unbelievably low amount of money in a depressed area. His charge for the laboratory work to the patient was very low if existent at all, depending on the ability to pay. But, his understanding of laboratory quality control had never been grasped nor learned. Also responsible for doing microbiology in this POL were the doctor's receptionist, cleaning woman and a high school student who came in after school. They were trained on-the-job by the doctor who was considered the director of the laboratory. This situation is entirely legal in most of the states in this country. It is not an exception that, in one area I surveyed, less than half of all of the unlicensed physician office laboratories ever made temperature checks of their laboratory incubators (the percentage for the licensed POLs was 100%) and not one unlicensed laboratory made quality control checks on the media used for throat cultures.

Even more revealing was the fact that only 18% of the unlicensed POLs in the survey participated in a proficiency testing program in microbiology or chemistry or hematology (again the licensed laboratory percentage was 100%). Participation in such a program is a relatively simple and inexpensive means of intervention which would considerably reduce the variability in physician office testing. I might add that, having set up my first physician office laboratory in Massachusetts in the early 1960s, this is not just a problem of POLs in Oregon, but is a growing trend nationwide.

People in the medical professions deal daily with symptoms and disease states. The symptom here is the lack of properly trained personnel in most unlicensed physician office laboratories. The disease, itself, is caused by the lack of any comprehensive, formal clinical laboratory training received by physicians, other than pathologists, while in medical school and/or internship. These physicians are the very people who go on to be the directors of their office laboratories, licensed or unlicensed. This is compounded by the claims of the user-friendly, walk-away technology equipment available in the health care marketplace which promise to generate great amounts of money for a doctor's practice with little or no need for trained personnel. As Curtis L. Bakken, M.D. from the Mayo Clinic in Rochester, Minnesota, stated in a major laboratory publication, "Nonpathologist physicians are often called on to act as laboratory directors and are legally responsible for the test results. Physicians are trained primarily to order the tests and interpret the results. Many of these physicians have little interest in the laboratory and know nothing about the different types of laboratory personnel, the subtleties of testing, the idiosyncratic personalities of 'foolproof' electronic equipment or even the basic concepts of quality control. He went on to say that, "For physicians already in practice, changes in medical school curricula and residency programs are irrelevant. Resources necessary to develop laboratory expertise are not readily available. Information and suggestions from clinical colleagues and equipment salesmen are probably not sufficient. Continuing education is the answer. Workshops, specifically designed training programs, and consultation from professional laboratorians are needed."

In addressing off-site testing facilities, Drs. Richard Belsey and Daniel Baer (who were also involved in the CDC/Oregon study) asked in The Medical Laboratory Observer (MLO), "Why does result reliability tend to be poorer in off-site testing facilities than in conventional laboratories? For one thing, physicians and others who supervise and process off-site testing generally have little or no background in laboratory medicine. They have limited experience in selecting tests and systems, training staff members, maintaining and troubleshooting analytic systems, or establishing a quality control program to insure the reliability of lab results." They also stated that, "When technologists run systems designed for off-site labs, their results are much less variable than those produced by health care workers likely to staff these facilities." They went on to say that, "It has become apparent that off-site testing facilities need on-going support from professional laboratorians to insure the quality of lest results." The CDC/Oregon survey showed the following:

CLINICAL LABORATORY TRAINING OF DIRECTORS OF PHYSICIAN OFFICE LABORATORIES

	Licensed Laboratories	Unlicensed Laboratories
General Practice	100%	0%
Internal Medicine	57%	33%
Family Practice	29%	47%

Of great interest and concern here is the fact that many physician directors of POLs, licensed or unlicensed, stated that they had not had any clinical laboratory training. (Oregon Administrative Rules state that, at the very least, a physician or accredited technologist must oversee laboratory testing to meet state licensure requirements.)

PROBLEM CASE #2

In clinical chemistry testing, accuracy refers to how close a measurement or an average of measurements is to the true value. Precision is the closeness with which repeated measurements agree. Standard deviation is one of the most useful estimates of precision. Determining accuracy and precision are indispensable in any quality control system and in the decision-making process in the laboratory and at the bedside. The product of the clinical chemistry laboratory is test results that are used for diagnosis and treatment of disease. I surveyed a POL whose personnel had been running liver enzyme tests on blood samples from residents in a small community because of a hepatitis A outbreak. The person running the analytical equipment, a non-laboratorian, had run out of what is referred to as a standard, a sample included with chemistry systems necessary for proper calibration and quality control of the machinery. It was decided that "the machine ran just fine without it anyway because it usually read the same" and the other full and part time on-the-job trained laboratory personnel using the equipment had not stated otherwise. There was no written documentation to verify this and no way to realize that the machine was not correctly calibrated. In the meantime, test results were interpreted and those people whose tests did not show any signs of the disease state went on with their daily lives, a few to jobs as food handlers in the community's restaurants popular with a large tourist trade. Others, students, were daily bussed to a larger city for schooling and many continued commuting to jobs outside the community. By the time I was on-site to conduct the third survey, patients previously testing 'within normal limits' had presented with the disease and, in the meantime, had infected others. It was realized that the initial chemistry screening results were invalid and the laboratory work had since been sent to a reference laboratory. I do not know if any loss of life occurred although it could have in someone more susceptible to a sudden and acute illness, such as an elderly person or a small child. I am aware that the outbreak went on for many more weeks and affected many more people in and out of the community than probably would have become ill with an earlier diagnosis of the disease through accurate laboratory testing. There were many needless days missed away from jobs and school not to mention the inconvenience of being ill and the effect this had on the daily lives of the afflicted. This type of erroneous laboratory data can result in misdiagnosis, improper medical treatment, prolonged hospital stays and has a great effect on health and health care costs.

In summary, the CDC/Oregon study showed that differences exist between licensed and unlicensed POLs in operational, personnel and performance characteristics. By all measures employed in the study, licensed physician office laboratories performed better in proficiency testing programs and on internal index of performance that did unlicensed POLs. Clear evidence exists to show that laboratories inspected for state licensure produce less variability in laboratory testing. While some physician directors may have the experience and expertise necessary to provide on-the-job training to laboratory personnel, it is unlikely to be the case in most physician office laboratories. The survey showed that physician directors in unlicensed laboratories tended to have less clinical laboratory training than physicians in the licensed laboratories and that many physicians, both in the licensed and unlicensed POLs, had no clinical laboratory training at all.

As a practicing clinical laboratory scientist with:

- 30 years of clinical laboratory experience, 12 as a chief technologist,
- a Baccalaureate Degree,
- a Masters Degree in progress,
- holding a registry with the American Society of Clinical Pathologists, certified by the National Certification Agency for Medical Laboratory Personnel,
- a National Board Member of the American Society for Medical Technology, and
- a Medical Technology Consultant with 4 years experience consulting to POLs,

I strongly recommend some form of regulation of physician office laboratories by state, federal or third-party carriers who can provide incentives by defining performance standards for reimbursement. Since completing the CDC study for the State of Oregon, I have made the conscious choice not to consult to unlicensed physician office laboratories. The knowledge and skill levels necessary for accurate completion of laboratory testing are usually lacking and the testing personnel generally do not understand the principles of day-to-day quality control and have trouble interpreting QC data. This cannot be effectively taught in an on-the-job setting to non-technical personnel who do not appreciate the difference between a proficiency testing program and day-to-day quality control as quality management tools. In a recent publication, a foreword by John W. Burnside, M.D., of Pennsylvania State College of Medicine stated, "The clinical laboratory must be understood before it can be used effectively. We physicians frequently misuse the laboratory. The costs of misuse—in terms of dollars, false positives, false negatives, repeated tests, and anxieties from misinformation—are very high."

Some experts have projected a 35% growth in physician office laboratories and predicting about $500 million worth of office laboratory testing by 1990. In light of these figures, I commend the Senate Subcommittee on Oversight of Government Management for holding this Hearing and creating an atmosphere for the exchange of ideas and experiences in relation to the POL phenomenon which has major, far reaching implications to our country's healthcare system in the years to come.

Testimony of Herbert W. Dickerman, M.D., Ph.D.
Director, Wadsworth Center for Laboratories and Research
New York State Department of Health
March 23, 1988
Senate Committee on Governmental Affairs
Subcommittee on Oversight of Government Management

Thank you for the opportunity to share in discussions on critical issues surrounding the federal government's role in assuring the quality of medical laboratory testing. The reliability of analyses performed by clinical laboratories, in all specialties and at all service sites including physician offices, must be assured in order to protect the health of our citizens. As Director of the Wadsworth Center of the New York State Department of Health, which has a long history of clinical laboratory regulation, would like to take this opportunity to review the regulatory issues before us and, to recommend the action at the federal level. I believe there is an urgent need for stimulation of state programs, coordination of existing federal agency resources, establishment of national minimum standards, encouragement of personnel education in laboratory specialties, and for expedited enforcement and remedial action.

The New York State Program

Nearly twenty-three years ago, on July 1, 1965, New York became the first state in the nation to initiate a certification and licensure program for clinical laboratories. The enabling legislation was the State's Laboratory Improvement Act of 1964. The federal government used New York's program as a model for legislation seeking to develop nationwide clinical laboratory standards -- the Clinical Laboratory Improvement Act (CLIA) of 1967. Since 1972, New York has remained the only state where clinical laboratories are exempt from federal interstate inspection, because our standards are acknowledged as equal to or more stringent than federal requirements.

In contrast to other state licensure programs, New York State's does not recognize other approval programs as an alternative to its own proficiency testing. Thus, all hospital based-laboratories are included in New York's inspection and certification program. We also inspect and certify laboratories outside the State if they accept specimens collected in the State.

The New York State program is based in the Wadsworth Center for Laboratories and Research of the New York State Department of Health. The Center is charged with responsibilities in both clinical and environmental sciences. Its activities include research, regulation, scientific and technical support to clinical and environmental laboratory improvement programs. In the clinical laboratory program, each proficiency testing specialty section is headed by a doctoral-level expert in the field. In addition to their public health service and research responsibilities, these section directors maintain scientific oversight of the proficiency testing program in their area of expertise.

The Environmental Laboratory Approval Program (ELAP), begun in 1986, is designed to be the most rigorous in the country, as is the clinical laboratory program. Building on experience gained in the clinical sector, ELAP produces its own semiannual proficiency testing materials and conducts annual inspections. The Wadsworth Center is thus able to meet specific State requirements for quality environmental testing. Future plans for this unit include closer integration with the clinical program in the areas of occupational health and environmental toxicology.

The Center's regulatory program sets standards for laboratory testing and inspects, tests, and licenses hospital and independent laboratories, as well as out-of-state laboratories doing business in New York State. In addition, Medicare surveys are conducted for laboratories located in New York City, which has a separate regulatory program.

The aim of our program is not to put laboratories out of business, but to assist them in achieving reliability of test results, crucial to the diagnosis and treatment of disease. Our governmental role is to assure the quality of information used for the care of patients thus, if a laboratory is deficient, it is subjected to immediate action including remedial education and if that fails to bring about the desired changes, the laboratory's license is revoked.

At the present time, 635 laboratories possess permits in a full range of clinical laboratory specialties. Despite the span of its regulatory mandate, the Wadsworth Center has demonstrated an ability to deal with rapid changes in laboratory technology. Within months of Food and Drug

Administration (FDA) approval of testing kits, the Center implemented inspection and proficiency testing for maternal serum alpha fetoprotein and human immunodeficiency virus.

Under New York State law, directors of all clinical laboratories must hold a Health Department certificate of qualification, and each laboratory must obtain an operating permit yearly. Laboratories are visited at least annually to monitor staffing, equipment, methodology, quality control, record-keeping, cleanliness and general effectiveness. Identified deficiencies result in additional visits. Personnel standards for supervisors and technologists have been established, and the credentials of laboratory staff are reviewed against these standards. Laboratories with inadequate staffing are required to recruit or redeploy personnel.

Proficiency testing is a vital component of the laboratory improvement program. Test specimens are mailed and/or carried to each clinical laboratory for analysis within a specified period. Laboratories failing to meet standards must improve proficiency through remedial training, successfully participate in retesting, or cease operation in categories failed. State-sponsored training courses in the form of seminars, workshops, and lectures are given periodically. Laboratory personnel are brought in for "in-house" training, and inspectors provide on-site instruction during inspection visits. A detailed description of the New York State proficiency testing program is attached.

Another feature of our program is that the total cost is recovered from fees assessed on permit laboratories. Fees are based on the total gross receipts of laboratories, with each laboratory paying a proportionate share of program costs based on its gross receipts from New York State testing. Last year, laboratories outside New York City reported gross receipts of $648,911,051. The procedure for the imposition of fees has been legislatively mandated.

The Federal Program

First, many of the problems and concerns with national regulation can be traced to the multiple governmental units involved in clinical laboratory oversight. The Food and Drug Administration (FDA), the Health Care Finance Agency (HCFA), and the Centers for Disease Control (CDC) all have clear statutory roles. Yet there is no coherent central philosophy guiding their activities. Management by memoranda of understanding between several agencies with separate agendas does not adequately assign responsibility and accountability.

The FDA is charged with approving equipment, kits and devices for *in vitro* diagnostic use. For example, the FDA has made available sophisticated technology to enhance physician's office diagnostic capacity. Yet there are no provisions to assure that these tests are performed correctly or that the results are accurate.

Another example is that, while FDA reqirements must be met if a kit or reagent is to be commercially marketed, labs that use their own techniques and reagents need no approval.

The HCFA program, by regulating only independent laboratories which bill Medicare, leaves many facilities without oversight. The HCFA Budget Call Letter dated July 7, 1987 established a target of only 60 percent coverage for routine surveys of independent Medicare laboratories, further diluting the benefits of its inspection program in other states.

As the Medicare state agency for New York, it is our experience that these inspections place too much emphasis on paper documentation of personnel qualifications and survey processing deadlines and not enough on quality assurance considerations. A streamlined process for stopping laboratories with marginal performance is clearly called for, balancing due process with the public need for quality assurance and immediate intervention. Currently, a laboratory can be quickly decertified for failure to pay the required permit fee or submit personnel documentation, yet a laboratory can often continue testing despite serious violations of quality control requirements. Administrative proceedings can be lengthy, resulting in marginal laboratories continuing to operate and to bill Medicare for long periods of time.

CDC used to perform proficiency testing of labs engaged in interstate commerce. It has been forced to abandon that program, leaving quality assurance to professional associations which provide voluntary testing programs with no regulatory authority or public accountability. There is no one central government entity responsible for guaranteeing quality assurance in labs. CDC has no direct responsibility for the technical operation of clinical laboratories, even though it is clearly the agency with the most expertise.

The Centers for Disease Control recently proposed standards to HCFA recommending national standards for proficiency testing for Medicare laboratories. This proposal calls for quarterly proficiency testing in all categories. At present the New York State program tests on a quarterly basis in all quantitative categories such as blood services, clinical chemistry, hematology, and oncofetal antigens, but semiannually in qualitative and semiquantitative programs such as bacteriology, diagnostic immunology, mycobacteriology, mycology, and parasitology. In addition, testing is conducted annually in cytogenetics and biennially in cytology.

First, the Wadsworth Center is not aware of any studies comparing the performance of laboratories participating in semiannual, quarterly, and annual proficiency testing programs. One could, with just as much justification, recommend testing laboratories, six, eight, or twelve times a year. The New York State program administers the number of tests in any given category which, in the scientific judgment of the professional directing the program, will provide a valid evaluation of participating laboratories' performance.

Second, it must be emphasized that our program exceeds in all instances the recommended total annual number of challenges. For example, the CDC recommends two challenges be sent quarterly in the bacteriology, mycobacteriology, and mycology program, i.e., a total of eight challenges per year. However, at present we submit, on an annual basis, 20 to 24 challenges in bacteriology, 20 challenges in mycology, and 10 challenges in mycobacteriology. We believe challenges, not frequency, are key to assessing a laboratory's ability to perform reliably.

Although both the CDC proposal and New York programs call for cumulative average scores to determine acceptable performance, the methods used in grading results differ. While a discussion of these differences would require a detailed analysis of each category, I can note that CDC's proposed minimum acceptable score for all categories is lower than that employed by our program in comparable categories. For example, the minimum acceptable score in our microbiology category is a cumulative yearly score of 80 percent, in contract to 70 percent recommended in the proposal.

More disturbing, from a regulatory point of view, is that the failing score proposed would usually be set at values beyond three standard deviations, yielding, in our view, too broad a range of acceptable results. Applying these guidelines, only one percent of examined laboratories would face failure. Our experience indicates more rigorous standards are appropriate. In its proposal, the CDC responded to this criticism as follows:

> Several comments were received that support the continued use of a two-standard-deviation limit to identify laboratories that are on the fringe of acceptable performance. Most of these comments came from groups who have had experience in using a two-standard-deviation limit to identify laboratories in need of improvement. The purpose of the uniform program is not to educate or improve laboratory performance but to protect

> the public from laboratory results that are so much in error that they might adversely affect patient care. Therefore, the focus of this program is on laboratories who are consistently providing inaccurate or imprecise results, not on those that are providing an occasionally deviant result.

We believe that protection of the public and improvement of laboratory performance are certainly not mutually exclusive, in fact, they must exist together. Rigorous testing standards do not discriminate against the laboratory producing an occasionally deviant result but, in multiple analyte testing, such standards do identify the chronically deficient laboratory. Furthermore, as I said earlier, we believe that education and professional improvement are a vital part of assurance.

Yet another weakness of the CDC proposal is the exemption from proficiency testing of Pap smear screening, as well as the categories of virology, histology, urinalysis, hemoglobinopathy, newborn screening, cytogenetics, drugs of abuse, and oncofetal antigens. This was discussed as follows in CDC's proposed guidelines:

> The Task Force considered each of these areas for inclusion in the program. They were not included in this proposal, however, either because the error rate has been found in the CDC program to be extremely low (urinalysis), or because there were concerns about obtaining suitable sample materials, or because of the lack of a professional consensus about what should be evaluated or how performance should be assessed.

New York State is very concerned that its current program, recognized as the nation's most rigorous, may not be recognized as meeting minimum Federal standards. This would result in either redesign of the State program to provide quarterly testing in all categories, despite lack of documentation that quarterly testing is necessary, or in supplementation of proficiency testing by New York State laboratories with less strict but quarterly programs.

HCFA has chosen to delegate much of its regulatory responsibilities to peer review programs such as those administered by the College of American Pathologists (CAP) or the Joint Commission (JC). These programs provide a valuable service in quality assurance. But they are not regulatory, nor are they designed to be. Their success is based on voluntary participation by hospitals and laboratories which want to do the best job possible. But this scheme lacks the crucial ingredient of public accountability -- the assurance that laboratory services offered to the public are of the highest quality and that those laboratories not complying with this standard will not be permitted to operate. Delegation of authority to peer review organizations is a clear abdication of the regulatory role.

Comparison of the New York State Program with CAP's

Both programs provide, through mailed test challenges and informational materials, a mechanism for monitoring of the overall performance of participating clinical laboratories. However, unlike CAP, New York State further ensures the quality of its permit-holding laboratories through required annual on-site inspections and use of hand-carried test specimens. The inspectors must be qualified medical technologists or cytotechnologists, with a minimum of six years' experience, who inspect all facets of laboratory operation, from incubator temperature monitoring charts to the disposal of infectious waste. In several clinical disciplines, such as clinical chemistry, cytohematology, and blood pH and gases, they also hand-carry proficiency test specimens which must be analyzed during the course of the consultants' visit. Such on-the-spot testing provides us with vital information on the routine operation of all clinical facilities in New York State.

As noted in the 1987 College of American Pathologists information brochure, "...each CAP survey is designed and supervised by laboratory professionals who volunteer their time and donate their talents -- nearly 100 practicing pathologists and consulting scientists." In short, CAP surveys are in effort formulated by committees, and test challenges are prepared by CAP staff. In contrast, New York State proficiency tests are developed by doctoral level professionals, who in addition to laboratory performance evaluation duties direct the ongoing day-to-day operations of State clinical diagnostic laboratories -- the public health reference laboratories of the Wadsworth Center. These directors all have firsthand experience with state-of-the-art clinical procedures. Moreover, all test challenges are assembled in these same diagnostic laboratories. In microbiology, for example, challenges represent recent clinical isolates obtained through actual diagnostic activities of State reference laboratories. Finally, all test challenges are "referenced", that is, sent to at least 10 acknowledged leading laboratories in the specialty. These reference laboratories authenticate test challenges and supply external quality control checks on all proficiency testing programs.

The aim of CAP surveys is to conduct a "...voluntary, educational, peer comparison program...". In contrast, New York State operates a mandatory, regulatory, and educational system. It assesses the performance of clinical laboratories ensuring optimum patient care as statutory requirement and promoting improvements in laboratory services provided by permit laboratories. Numerous reports in the literature have demonstrated that voluntary proficiency testing simply does not perfect laboratory performance as well as a mandatory program does. When laboratories must perform to obtain an operating permit, greater incentive exists to achieve state-of-the-art standards.

New York State, unlike CAP, also offers proficiency testing in exfoliative cytology and oncofetal antigens, and shortly a program in toxicology - chlorinated hydrocarbons will be available.

Both systems provide individual laboratory evaluation and summaries of all participants' performance. While CAP's are for the most part statistical surveys, New York State furnishes not only statistical comparisons of performance, but also a "critique", a detailed description of test challenges, the techniques used in evaluating each challenge, and the laboratories' experience with each technique. In short, participating laboratories not only learn how they performed quantitatively, but also receive a complete discussion of procedures and techniques for analysis of all test challenges.

In addition to critiques, New York, unlike CAP, mandates remedial educational training of failing laboratories. The nature of these educational programs differs from discipline to discipline, but in each instance the deficient laboratory must demonstrate to the director of the particular test section that further training and education has been successfully completed. In many cases these remediation programs consist of bench training at the diagnostic reference laboratories in Albany. Through the personalized attention of the section director, failed laboratories are afforded remediation to meet their specific needs. In addition, many of our diagnostic laboratories offer routine workshop programs to all participating laboratories. In all instances, the objective is to improve performance to ensure better patient treatment and care.

Other Regulatory Issues

Laboratories in hospitals with Joint Commission (JC) approval are exempt from federal oversight. Only in hospitals which have lost JC endorsement is HCFA authority exercised; in New York State, this represents only three of 277 hospitals. To our knowledge, JC has never revoked approval of a hospital based on deficiencies in its laboratory. Furthermore, JC surveys are not conducted annually, and a significant delay in producing survey reports is often observed. Delegation of authority for laboratory inspections to JC should be reviewed, given the lack of frequency and comprehensiveness of the program.

Our experience with JC laboratory evaluation indicates that its inspections of laboratories are superficial in scope and detail. Nor does JC require that a laboratory perform successfully in proficiency testing, only that it participate. New York State hospital laboratories are often cited for inadequate frequency of proficiency testing, despite the stringency of our program, while serious performance or record keeping deficiencies can be overlooked.

Another concern is lack of quality assurance in laboratories located in physicians' offices and other service sites. While I understand that by January of 1989 HCFA will require some oversight of physician office laboratories performing 5,000 or more tests, I have yet to see the regulatory language for this requirement. However, if the criteria are simply 5,000 tests billed to Medicare, physician office laboratories serving young women and children will continue to go unregulated, and there is no available mechanism to identify those offices requiring regulation.

Of special interest is the growing phenomenon of reading Pap smears results in physician offices. The Wadsworth Center, at present prohibited by statute from regulating testing in physician offices, is proposing legislation calling for a survey to determine the nature and extent of Pap smear testing in New York State. While we are concerned with physician office testing overall, the area of Pap smears is critical at this time. If some certified laboratories under a certain level of regulation are missing cervical cancer, what is happening in the doctor's office?

Many primary ambulatory care clinics and rural health centers, which must provide certain tests to receive federal approval, are under no regulatory oversight at all, and are not required to participate in either state or HCFA programs. Other clinics, many with Federal funding, also fall into this regulatory void. This issue must be addressed forthwith, as new technology makes on-site testing more accessible and the proliferation of outpatient primary care facilities leads to escalating patient visits. The Wadsworth Center is attempting to respond in this area and expects to have a program in place shortly.

We can only ask -- what is the quality of testing outside New York State? Other deficiencies in federal regulation include employee drug testing, occupational safety and health, WIC program eligibility criteria, and testing for insurance underwriting purposes. Regardless of the setting of the test, we believe that the entire population is entitled to quality assurance in laboratory testing. The current regulatory patchwork clearly does not further this objective.

Recommendations for Federal Action

New York State believes that regulation of laboratories belongs at the state level, for government closest to the regulated parties is most effective. In fact, a network of state agencies performing Medicare surveys for HCFA already exists and can be built upon.

The federal government must establish national minimum standards for laboratory testing and take steps to stimulate state regulation, an original goal of the Clinical Laboratory Improvement Act. All testing of human specimens, whether in hospitals, clinics, or physician offices, and for occupational health, employee drug testing, and insurance underwriting purposes, must be regulated. Through grants to states, encouragement should be provided for development of laboratory evaluation programs, with ongoing support based on assessment of laboratory fees, as in New York.

Federal technical assistance to states for assuring quality of clinical laboratory services should be centered in one organization or facility with the necessary technical expertise. This organization should exercise oversight of all federal activities involving clinical laboratory testing, such as the Veterans Administration program, Occupational Safety and Health and the Maternal and Child Health Block grant to ensure quality of laboratory services, regardless of purpose.

While clinical laboratories must be protected against arbitrary and capricious enforcement activities, an expedited legal process, to halt patient testing in instances of documented deficiencies in quality or proficiency, is essential to safeguard the public health.

In other areas, a national direct-billing law, similar to New York's, which requires that laboratories bill the patient or the insurance carrier rather than the physician, would eliminate incentives to choose laboratories based on cost considerations, and would assure that the public knows where tests are actually performed.

One of the most critical areas in this context is the shortage of qualified medical technologists and cytotechnologists, absolutely essential for quality laboratory services. The closure of many training programs has exacerbated the shortage of technologists. Health manpower development funds directed to medical technologist and cytotechnologist educational programs are desperately needed. Finally, action must be taken to improve the status, advancement, and wages of medical technologists, cytotechnologists, and other laboratory personnel to keep them in the field. Current consideration to eliminate personnel requirements must cease.

In closing, I believe we must assure the validity and reliability of laboratory testing services -- whether in the laboratory, hospital, clinic, or office -- to guarantee protection of the public's health.

TESTIMONY OF

Josephine Bartola, J.D., Director
Division of Laboratory Improvement
Bureau of Laboratories, PA Dept. of Health

Before the

Subcommittee on Oversight of Government Management

Committee on Governmental Affairs

United States Senate

March 23, 1988

Mr. Chairman and Members of the Subcommittee:

I am Josephine Bartola, Director of the Division of Laboratory Improvement from the Pennsylvania Department of Health, Bureau of Laboratories. Thank you for the invitation to appear today to discuss Pennsylvania's efforts in attempting to ensure quality laboratory services for its citizens.

Pennsylvania has a long legislative history of regulating clinical laboratories, which parallels the growth of the field of laboratory medicine itself. The first statute, enacted in 1951 when laboratory medicine was a young, emerging science, was developed as independent, profit oriented clinical laboratories began to appear throughout the state, offering testing to the public. Since these were operated by non physicians, the legislature became concerned and wanted to ensure that only qualified individuals be permitted to conduct clinical testing. Up to this time, most clinical tests were performed in hospital laboratories and state health departments. However, the Act applied to non physician directed laboratories only and required little more than registration with the Department of Health.

By 1961, the field of laboratory medicine had grown substantially. As a result of new technology developed, many more tests were available and physicians were placing considerably more reliance on test results for diagnosis and treatment. The legislature acted again, this time amending the statute to require the development of standards for clinical testing and periodic monitoring to verify the accuracy of the work of the laboratory. The amendment was extended to include all independent laboratories, even those directed by physicians, but hospital and physician office laboratories (POL's) continued to be excluded.

However, by 1972, laboratory medicine had become a large industry in Pennsylvania and elsewhere, made possible by the enormous strides in technology. In addition, the introduction of federal standards for Medicare in 1966 and Interstate laboratories in 1967 had spurred industry to produce better reagents, standard and control materials so more reliable testing was possible. At this time, the independent laboratory community in Pennsylvania, long subject to regulation, convinced the legislature to remove all exemptions from the Act and require all clinical laboratories to meet minimum standards of performance. So today, Pennsylvania is the only state where all clinical testing is subject to licensure no matter where it is performed. This includes hospital, independent, industrial, county and physician office laboratories. There are presently 6174 laboratories in the Pennsylvania program, consisting of:

300	Hospital laboratories
274	Independent laboratories
5600	POL's:
	3150 Level I
	1400 Level II
	1050 Level III

SCOPE OF REGULATION

Pennsylvania licensure requirements for hospital and independent laboratories are essentially equivalent to the federal standards developed for Medicare certification and interstate licensure. These include specific academic credentials and experience at the director supervisory and technologist levels, an annual on-site survey, documented internal quality control systems, acceptable participation in an approved proficiency testing program, current procedure manuals and appropriate record keeping. Since the independent laboratories were already subject to the federal programs, the 1972 amendment required little change in regulation of these facilities. But most hospital laboratories were subject to quality control and proficiency testing requirements for the first time.

However, in attempting to apply the existing state regulations to the POL's, the Department encountered considerable difficulties. Most of the POL's simply could not qualify for licensure. The personnel lacked formal laboratory training for the most part, the physicians themselves had little or no formal laboratory training and were not aware of basic principles of good laboratory practice. Another factor that had to be considered in implementing regulations in the POL was the enormous cost of applying the full licensure requirements to the hundreds of POL's in our state, many performing only limited testing. There was also a question of whether this approach would be a prudent expenditure of public funds, even if funds were available, if an alternative system could be designed for POL's performing limited testing that could be expected to reasonably protect the patient without the necessity of imposing full licensure requirements.

Working with representatives from the Pennsylvania Medical Society and our statutory Advisory Committee, that consists of pathologists, chemists and microbiologists from laboratories in the state, a questionnaire was developed and distributed to approximately 25,000 licensed physicians to determine the range of testing actually performed in their offices. The results of the survey showed a wide range of testing, from those performing only a few tests to those conducting a full service laboratory. It also revealed the types of tests most frequently performed, i.e., urinalysis, blood glucose by finger stick, hemoglobin and/or hematocrit.

Utilizing the information generated by the survey, we developed our current three-level system for regulating POL's which has been aggressively implemented since 1980. These levels are described in Table 1.

TABLE 1

Level I

A. Urinalysis - chemical

B. Whole Blood glucose - stick method

C. Urinalysis - microscopic and specific gravity

D. Pregnancy tests

E. White cell count

F. Hematocrit

G. Hemoglobin

H. Sedimentation rate

I. Primary culturing

J. Occult blood

K. Pinworms

L. Trichomonas vaginalis

M. Sickel cell screens

Level II

A. -M. (Level I)
N. Differential count
O. Prothrombin time
P. Blood glucose
Q. Test for mononucleosis
R. Throat screens
S. Urine screens and colony counts
T. Gram stain

Level III

Full-service laboratory

The system was designed to reduce the regulatory requirements for those POL's performing limited testing, provided the requirements outlined for each level are met and provided testing is limited to the physician's own patients. It is also designed to accommodate changes which may result as new technology continues to emerge.

Practically, how is the system implemented? Initially, a questionnaire is mailed to the POL, to determine the range of testing performed. Based on the information provided, the physician is informed in writing of the level at which the laboratory is performing and the requirements at that level.

REQUIREMENTS AT EACH LEVEL

Level I

The laboratory qualified at Level I is registered and provided with the state quality control requirements, but no on-site visit is made to the POL to determine if they are actually in compliance.

Nothing more is required at Level I unless the POL increases its range of testing, which would place it into a higher level. The Level I laboratories are encouraged to utilize the expertise of the Bureau of Laboratories for consultation and to keep abreast of the many changes occurring in the field of laboratory medicine. They are also placed on a mailing list to receive the Bureau NEWSLETTER, workshop announcements, and other communications of technical interest, to update them on the changes occurring in this dynamic field. Fifty-six percent of the POL's perform at Level I.

Level II

If the POL is eligible at Level II, there are a few additional requirements. The POL must adhere to the state internal quality control requirements and the laboratory is required to participate in an approved proficiency testing program for the categories of tests performed and results must be provided to the Department. However, the POL does not receive an on-site visit at this level and there are no personnel requirements. However, to monitor compliance with the Department's requirements, a self-evaluation form is distributed each year which solicits specific information regarding the quality assurance practices utilized. A copy of the form is attached as Appendix "A". Our personnel have frequent telephone contacts at this level to offer consultation and advice about recommended procedures, standards and controls that are necessary and sources of reagents and materials. This is an extremely important aspect of the program since we found that more than 50% of the individuals performing the testing had no laboratory training. The POL has traditionally relied on the claims of sales representatives for both the selection of instruments and test materials and for training of the operator. Most POL's function in isolation with little or no contact with the laboratory community, the regulating agencies, or other laboratories. As a result, the typical POL had not kept pace with the regulated laboratories with respect to the establishment of quality assurance programs. There were exceptions, of course, but these were in the minority. Therefore, an important objective is to establish a rapport with the POL to encourage the individual performing the testing to use the consultation services of the Department. POL personnel have been very responsive to this approach.

Twenty-five percent of the POL's perform at Level II.

Level III

If the POL is eligible at Level III, it is subject to full licensure and, of course, more stringent requirements. In addition to adherence to quality control regulations and participation in a proficiency testing program, the POL must meet certain personnel requirements and will receive an annual on-site visit. Physicians performing testing on their own patients only, who do not have the requisite clinical laboratory experience, are issued a two-year provisional licnese. After they have participated successfully for two years in an approved proficiency testing program, and have undergone two successful on-site surveys, the provisional is removed. However, physicians [illegible]fering testing services to other than their own patients must qualify for full licensure. No provisional license is permitted. Consultation and advice about recommended procedures, standards and controls that are necessary is an important aspect in all contacts with POL's.

Nineteen percent of the POL's perform at Level III.

SANCTIONS AVAILABLE UNDER PENNSYLVANIA LAW

The Pennsylvania statute permits revocation of a license for a number of violations including consistent error based on faulty techniques, consistent failure to correct serious deficiencies noted during on-site survey and for all violations of the regulations which may jeopardize the integrity and reliability of the test results.

PROFICIENCY TESTING REQUIREMENTS IN PENNSYLVANIA

All hospital, independent, Level II and III POL's are required to participate successfully in an approved proficiency testing program. The programs currently approved are listed in Appendix "B". In addition, the Bureau of Laboratories conducts its own proficiency testing programs in virology, blood alcohol, lead, erythrocyte protoporphyrins, drugs of abuse and a program for physician office laboratories performing 3000 tests a year or less.

Laboratories enrolled in a program other than a Pennsylvania program must agree to have their proficiency test results forwarded to the Department by the testing agency. All results are monitored and action taken as necessary.

Number and Frequency of Challenges

The Department accepts the number and frequency of challenges for those private programs approved. The number and frequency of challenges of the proficiency testing programs conducted by the Bureau of Laboratories are described in Appendix "C".

Grading Criteria

The grading criteria utilized for both private programs and those conducted by the Bureau of Laboratories are described in Appendix "D".

Unsuccessful Participation

Successful participation in an approved proficiency testing program is one of the requirements for maintaining a Pennsylvania clinical laboratory license. It is also a requirement to maintain a federal laboratory license to operate in interstate commerce and to maintain certification for reimbursement under the Medicare program. Failure to perform acceptably results in the following action:

Constituent	Action
Blood Alcohol	Approval removed after two (2) successive failures. Approval restored after acceptable performance in one evaluation (usually after 3 months).
Lead	"
Erythrocyte Protoporphyrin	"
Drugs of Abuse	See Appendix "E" for complete discussion.
All Other Constituents:	
Single failure	Laboratory informed and advised to take corrective action. No citation issued but failure recorded.
Two (2) consecutive failures in a single constituent or area	Laboratory cited by letter and a written plan of correction required within ten (10) working days of citation. Plan must describe the investigation made and the corrective steps taken.

All other constituents:	Action
Failure in three (3) consecutive evaluations or in three (3) of four (4) evaluations in a single constituent or area	Approval to perform withdrawn. Approval restored after the laboratory as performed acceptably in two (2) subsequent evaluations (usually a period of six (6) months).

RECOMMENDATIONS FOR FEDERAL ACTION

Ensuring quality assurance and accountability in the laboratory requires the consistent efforts of everyone involved in the process. This includes not only the federal government but also state governments, professional organizations, the manufacturers of instruments and reagents and the intellectual integrity of the individuals responsible for the testing. The nature of laboratory testing, with the number of variables operating in any given test, requires daily, consistent internal quality control and periodic external monitoring. Periodic monitoring, provided by state and federal regulators or private programs, has been fragmented and inconsistent.

Therefore, the following recommendations are submitted:

1. The federal government should demonstrate its leadership role by establishing national standards of performance for all laboratory testing no matter where it is performed. Standards should be developed based on the level of complexity of the testing performed rather than by the volume of tests done. Many physician office laboratories, performing less than 5000 tests per year, perform complex tests which require independent judgement and adequate training. These should be monitored.

2. A national proficiency testing program should be designed and participation required of all laboratories, commensurate with the level of work performed. Acceptable grading criteria should be established and uniform sanctions applied.
3. The federal government should provide assistance in developing training programs, particularly for physician office laboratories. Our experience in visiting these laboratories during the last seven years has emphasized the need. With good training, we have found that even non laboratory personnel can perform simple procedures reliably. Without good training, they often do not perform well.
4. Finally, government intervention is essential because voluntarism has not worked. Some sanctions are a necessary part of an effective monitoring program. The regulatory burden need not be excessive, however, it must be consistent. We should not overlook the excellent laboratory services provided by many laboratories throughout the nation everyday. For the most part, these are the laboratories that have been subject to regulation and have been required to meet specific standards for more than 20 years.

APPENDIX "A"

G. DERMATOPHYTE SCREENS

1. WHAT MEDIA AND/OR KITS ARE USED? ____________________

2. ARE THE MEDIA (KITS) QUALITY CONTROLLED? ____________________

3. HOW OFTEN? ____________________

4. WITH WHAT ORGANISMS? ____________________

5. WHERE IS QUALITY CONTROL PERFORMED? ____________________

H. GRAM STAIN

1. IS THE GRAM STAIN CHECKED FOR CORRECT STAINING QUALITY? ____________________

2. HOW OFTEN? ____________________

3. WHAT ORGANISMS ARE USED? ____________________

J. GENERAL QUALITY CONTROL

1. ARE QUALITY CONTROL RESULTS RECORDED? ____________________

2. ARE QUALITY CONTROL RESULTS REVIEWED? ____________________

3. BY WHOM? ____________________

4. HOW OFTEN? ____________________

K. ADMINISTRATIVE

1. ARE YOU ENROLLED IN A PROFICIENCY TESTING PROGRAM? ____________________

2. WHICH ONE? ____________________

3. DOES THE STAFF PERIODICALLY REVIEW THE STATE'S QUALITY CONTROL REQUIREMENTS? ____________________

4. HAVE ALL NEW PERSONNEL REVIEWED THE STATE'S QUALITY CONTROL REQUIREMENTS? ____________________

5. DOES THE DIRECTOR ASSURE THAT CHANGES IN QUALITY CONTROL REQUIREMENTS PUBLISHED IN THE BUREAU OF LABORATORIES NEWSLETTER ARE MADE IN THE LABORATORY'S QUALITY CONTROL PROTOCOL? ____________________

Commonwealth of Pennsylvania

Department of Health

SELF-EVALUATION QUESTIONNAIRE 1987

LEVEL II LABORATORY

PLEASE CHECK OFF TESTS BEING PERFORMED IN YOUR LABORATORY

URINALYSIS [___]
GLUCOSE [___]
CHEMISTRY (OTHER) - PLEASE LIST [___] ____________ ____________
PREGNANCY [___]
RHEUMATOID FACTOR [___]
INFECTIOUS MONONUCLEOSIS [___]
AUTOMATED HEMATOLOGY [___]
DIFFERENTIAL COUNT [___]
HEMOGLOBIN [___]
HEMATOCRIT [___]
PROTHROMBIN TIME [___]
THROAT CULTURES SCREENS [___]
DIRECT ANTIGEN (GROUP A BETA STREP) [___]
URINE CULTURE SCREENS [___]
DERMATOPHYTE SCREENS [___]
GRAM STAINS [___]
OTHER (PLEASE LIST) [___[____________ ____________

SIGNATURE OF DIRECTOR: ____________________

SIGNATURE(S) OF TECHNICAL PERSONNEL: ____________________

PROFICIENCY TESTING PROGRAMS APPROVED BY PENNSYLVANIA

General Programs

American Association of Bioanalysts (AAB)
American Society of Internal Medicine/Medical Laboratory Evaluation (ASIM/MLE)
College of American Pathologists (CAP)
Pennsylvania Low Volume Proficiency Testing (LVPT) - open only to Level 2 physicians' office laboratories and certain other laboratories doing very low volumes of testing

Blood Gases

American Dade
American Thoracic Society
Ciba-Corning Diagnostic Corp.
College of American Pathologists
Curtin-Matheson Scientific, Inc.
Organon-Teknika Corp. (previously General Diagnostics)
Radiometer America
RNA Medical Corp.

Toxicology

For Blood Alcohol, Blood Lead, Erythrocyte Protoporphyrins, and Drugs of Abuse testing, the only approved programs are those administered by the Bureau of Laboratories, Division of Chemistry and Toxicology.

APPENDIX "B"

PROFICIENCY TESTING PROGRAMS CONDUCTED IN PENNSYLVANIA

Number and Frequency of Challenges

Program	No. of Challenges		Frequency
Physician Office Laboratory (3000 tests or less)	Bacteriology	1 specimen for throat screen 1 specimen for urine screen 2 slides for Gram's stain	4 times a year
"	Serology	2 specimens for infectious mononucleosis 2 specimens for rheumatoid factor 2 specimens for pregnancy	2 times a year
"	Chemistry	2 specimens for glucose, urea nitrogen, creatinine, uric acid, cholesterol, triglyceride, sodium, potassium, digoxin, theophylline	4 times a year
"	Hematology	2 specimens for hemoglbin, hematocrit, red and white cell counts 2 specimens for prothrombin time 2 slides for differential count	4 times a year
"	Urinalysis	2 specimens for protein, glucose, ketone, blood, pH, bilirubin	4 times a year

All laboratories performing the following must be enrolled in the Pennsylvania programs:

Drugs of Abuse	4 specimens	4 times a year
Blood Alcohol	5 specimens	4 times a year
Lead	4 specimens	4 times a year
Erythrocyte Protoporphyrin	4 specimens	4 times a year
Virology	5 specimens	Once a year

Note:
The number and frequency of challenges offered by the private proficiency testing programs approved and listed in Appendix "A" are accepted.

APPENDIX "C"

GRADING CRITERIA FOR PROFICIENCY TESTING

Private Programs	Grading Criteria
College of American Pathologists American Association of Bioanalysts American Society for Internal Medicine/MLE Blood Gas Programs	Computer printouts and tapes are received. We do not regrade these. If a result is flagged as unacceptable or outside their limits, however those limits are set, it is not acceptable for us. For any given test, glucose, fungus identification, etc., with two or more specimens, the laboratory must get 66.6% of the specimens correct to receive a passing grade for the test. Thus, if there are two specimens, the laboratory must get both correct. If there are six specimens, 4 correct.

Pennsylvania Programs	
Drugs of Abuse	See Appendix "E" for complete description
Blood Alcohol	Limits set at ± 2 SD around $\bar{x}$ Only 1 error permitted.
Lead	Limits set at ± 2 SD around $\bar{x}$ Only 1 error permitted.
Erythrocyte Protoporphyrin	Limits set at ± 2 SD around $\bar{x}$ Only 1 error permitted.
Virology	A grade of 70% is passing.
Physician Office Laboratory Program: (3000 tests or less)	
Chemistry	Limits set at ± 2 SD around method ± Both of 2 specimens must be acceptable.
Hemoglobin	Limits set at ± 2 SD around method ± Both of 2 specimens msut be acceptable.
Differentials	Limits set at ± 2 SD around ± of each cell type may be modified by reports of reference labs (5-6 hospitals) "red cell evaluation" and "clinically significant findings" based on 100% agreement by reference labs; i.e., a participant must report a finding that all of the reference laboratories found - for count, one cell type may be out of range; if it does not change interpretation - if 2 cell types out slide result is unacceptable. Both of 2 specimens must be acceptable.

APPENDIX "D"

Grading Criteria for Proficiency Testing (continued)

Pennsylvania Programs	Grading Criteria
Protimes	Limits set at ± 2 SD around mean of ratio result/normal control. Both of 2 specimens must be acceptable.
Urinalysis	Limits set by what we know we added to normal, negative specimens results may be invalidated (and not graded) by serious (less than 80% concensus) disagreement by participants - all constituents in both specimens must agree to be acceptable.
Pregnancy, Mono, RF	Limits set by what we know we sent out - positive and negative pregnancy prepared in house from staff specimens, positive mono and RF are commercially prepared controls, negative mono and RF are 3.5% albumin in sterile physiological saline - results may be invalidated by serious disagreement by participants. Both of two specimens must be acceptable.
Bacteriology	
Throat Screens	Limits based on what we know we sent - organisms confirmed originally by Bureau of CDC - must report as Group A Strep "detected" or "not detected" on specimen, must be correct.
Urine Screens	Limits based on what we know we sent - organisms confirmed originally by Bureau of CDC - must report to extent report patient results. One specimen, must be correct.
Gram Stain	Limits based on what we know we sent - organisms originally confirmed by Bureau of CDC Both of two specimens must be acceptable.

Any specimen may be disallowed and not graded if a sudden drastic decrease in participant success suggests a specimen deterioration or incompatability problem has occurred.

Commonwealth of Pennsylvania

Department of Health

BUREAU OF LABORATORIES
Pickering Way and Welsh Pool Road
Lionville, PA 19353

Telephone (215) 363-8500

GRADING SYSTEM FOR URINE DRUG ANALYSIS PROFICIENCY TESTING PROGRAM

Introduction

In order to meet the demand for improved reliability in the testing of urine for abused substances, the Division of Chemistry and Toxicology, Bureau of Laboratories is revising its proficiency testing program for laboratories who offer this service. Proficiency testing is conducted in accordance with §5.50 of the Regulations (28 Pennsylvania Code) to the Commonwealth's Clinical Laboratory Act (35 P.S. §§2151 *et seq*.). The revised proficiency testing program will permit the Bureau to monitor the performance of laboratories that conduct urine drug testing for diagnostic purposes as well as those that perform the determinations to detect drug abuse in the workplace or for other forensic purposes. The grading system described below will be used commencing with the July 1987 survey to evaluate laboratories participating in the proficiency testing program for approval to determine abused substances in urine. The new system will evaluate screening *and* confirmatory testing capability separately, and laboratories will be approved to perform screening and/or confirmatory testing on the basis of their demonstrated proficiency.

Initial Approval

Laboratories applying for admission to the program as either screening or confirmatory testing facilities will be required to demonstrate errorless performance in the determination of those analytes for which they offer detection services. This is considered a prerequisite for approval of laboratories performing either type of determination.

Continued Approval - Screening Laboratories

Errors of either the false negative or false positive type may occur when a laboratory performs screening determinations. False negative errors are a serious problem since persons who use drugs may not be detected. False positive findings, while also a problem, are not as serious, since confirmatory testing should be performed before any action is taken which affects the specimen donor. Therefore, errors in screening will be handled as follows:

False Negative Errors - First Occurrence: The screening laboratory will be advised of the error(s) and instructed to determine the cause of the error(s) and take remedial action. During this period, the laboratory may continue to offer testing services, unless the error(s) are considered highly significant. A report detailing the cause of the problem, and the corrective action must be submitted to the Bureau of Laboratories within ten calendar days. Failure to notify the Bureau of Laboratories of the corrective action will result in loss of approval to perform screening determinations.

False Negative Errors - Second Occurrence: If a screening laboratory reports a false negative in a second consecutive survey, approval to offer urine drug screening services will be removed and will not be reissued until the laboratory demonstrates errorless performance in a regularly scheduled proficiency survey. However, if the laboratory is able to provide acceptable documentation of successful resolution of the problem, interim approval will be considered.

False Positive Errors - First Occurrence: Screening laboratories will be considered to have performed unsatisfactorily in a survey when two or more false positive results are reported. Facilities reporting any false positive results will be expected to take immediate corrective measures.

False Positive Errors - Second Occurrence: If a screening laboratory reports two or more false positive results in a second consecutive survey, approval to offer urine drug screening services will be removed and will not be reissued until the laboratory demonstrates errorless performance in a regularly scheduled proficiency survey. However, if the laboratory is able to provide acceptable documentation of successful resolution of the problem, interim approval will be considered.

The Bureau of Laboratories will scrutinize proficiency testing results to evaluate proficiency from survey to survey. Screening laboratories which are found to have an erratic record of performance will be required to take corrective action to improve their reliability. Laboratories that demonstrate continuing inability to perform with consistent reliability will be required to discontinue testing until they can demonstrate acceptable capability.

Continued Approval - Confirmatory Laboratories

Since it is imperative that laboratories performing confirmatory testing obtain reliable results, additional proficiency testing requirements are placed on these facilities. To be acceptable, the confirmatory procedure must utilize a different principle of analysis than the screening procedure. The confirmatory testing procedure should also be at least as sensitive as the screening procedure. For most abused substances, gas chromatography-mass spectrometry is recommended as the method of choice for performing confirmatory analyses where the results could be applied in a manner that would adversely affect the person whose urine was analyzed. This would particularly apply to drug testing in the workplace and other situations with forensic implications.

For grading purposes, a false positive or false negative confirmatory result is a serious problem and must be corrected before the laboratory can be permitted to continue testing.

Erroneous Result(s) - First Occurrence: The confirmatory testing laboratory, upon receipt of notification of the error, must immediately discontinue testing, determine the cause of the error, and take remedial action. Documentation of the cause of the problem and corrective measures taken must be submitted to the Bureau of Laboratories. When the corrective action has been reviewed and found to be acceptable by the Bureau, the laboratory will be advised, in writing, that it may resume testing, however, its status in the program will be changed to probationary. Regular approval will again be reissued after errorless performance in two consecutive regularly scheduled surveys. If doubt exists as to the effectiveness of the remedial action, the laboratory may be required to perform errorlessly in a proficiency survey before issuing the probationary approval.

Erroneous Result(s) - Second Consecutive Occurrence: Confirmatory testing laboratories that report erroneous findings in a second consecutive proficiency survey will be required to cease testing immediately upon notification by the Bureau of the testing results. The facility will be required to determine the cause of the error(s) and initiate corrective measures. Documentation of the cause of the problem and remedial action must be submitted to the Bureau for review. If acceptable, the laboratory will be sent test specimens in the next regularly scheduled proficiency survey. Pending errorless performance in the survey, the laboratory will be readmitted to the approval program on a probationary basis. Errorless performance in two consecutive surveys will then be required before regular approval status is reissued.

Laboratories which demonstrate a record of erratic performance in confirmatory testing may be required to discontinue testing until they have improved their testing methods and can demonstrate consistently reliable performance.

On the basis of proficiency testing results, laboratories will be approved to perform screening and/or confirmation testing. Lists of approved laboratories offering these services will be compiled and published semiannually in the Pennsylvania Bulletin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Washington, D.C. 20201

STATMENT OF
LOUIS B. HAYS
ASSOCIATE ADMINISTRATOR FOR OPERATIONS
HEALTH CARE FINANCING ADMINISTRATION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
MARCH 24, 1988

Introduction

Mr. Chairman and Members of the Subcommittee, I am Louis B. Hays, Associate Administrator for Operations of the Health Care Financing Administration (HCFA). I welcome the opportunity to discuss our ongoing efforts to ensure that clinical laboratories meet high quality standards of performance. While we believe that the overall quality of laboratory performance is acceptable, we recognize that there has been a growing concern on the part of the Congress and the public about the quality and accuracy of laboratory testing. We share that concern and have been working for over a year on this difficult problem. I am pleased to report that we will soon propose comprehensive regulatory reform to address the major quality issues.

Background

Let me preface my remarks with a brief background on the regulation of clinical laboratories. There are two major Federal programs which regulate clinical laboratories, and both are administered by the Health Care Financing Administration. The first is the Medicare program which covers both hospital laboratories and independent laboratories. By meeting Medicare's conditions of participation, laboratories are certified to receive payment for services provided to Medicare or Medicaid patients.

The second Federal program regulating clinical laboratories resulted from the Clinical Laboratory Improvement Act of 1967

(CLIA). Regulations under CLIA apply to laboratories performing laboratory testing on specimens in interstate commerce. The Centers for Disease Control (CDC) had the initial responsibility for the implementation and administration of the CLIA program. This responsibility was transferred to HCFA in 1979 to consolidate programs and reduce duplicative activities in assuring that laboratories meet quality standards.

There are over 12,000 laboratories participating in Medicare and Medicaid. Of these, about 4,500 are independent laboratories and 6,600 are in hospitals. Under CLIA, there are 1,520 laboratories which meet the CLIA requirements, of which 1,320 are also Medicare certified. An additional 519 laboratories perform interstate testing but are exempt, under law, from CLIA regulation by virtue of accreditation by the College of American Pathologists or licensure by the State of New York.

Survey and Certification

The primary mechanism the Federal government uses for assuring that laboratories meet quality standards is the Medicare survey and certification process. State agencies, usually State Health Departments, have agreements with the Department to survey laboratories' compliance with regulatory conditions of participation.

Hospital laboratories accredited by the Joint Commission on the

Accreditation of Health Care Organizations or the American Osteopathic Association are deemed, under the law, to meet quality standards comparable to Medicare. What this means is that JCAHO and AOA are responsible for the timing and manner of surveying hospital laboratories. Currently, about 40 percent of JCAHO hospital laboratories are surveyed for accreditation purposes by the College of American Pathologists.

There are seven major laboratory conditions of participation that Medicare laboratories must meet. These conditions include:

- compliance with relevant State and local laws;
- qualifications for the laboratory director;
- standards for the supervision of laboratory testing;
- participation in a proficiency testing program;
- qualifications for technical personnel;
- management requirements such as the maintenance of adequate records and procedure manuals for testing methodologies; and
- an acceptable quality control program;

To assure that conditions of participation are continually met, the State agencies conduct annual, on-site surveys of independent laboratories which are not announced in advance. The State notifies nonaccredited hospitals prior to the annual survey. Accredited hospitals laboratories are subject to announced surveys by the JCAHO or AOA every 2 to 3 years. At the time of the Medicare survey, State agencies also review CLIA laboratories' compliance with standards that are comparable to those under Medicare for independent laboratories.

State agencies also perform surveys on a sample of accredited hospitals or in response to a complaint to validate that these hospitals continue to meet quality standards. If serious deficiencies are identified, the State agencies are responsible for assuring correction or taking action to terminate the hospital's participation in Medicare. Generally, the State validation surveys show overall agreement with the accreditation surveys.

Similarly, Federal surveyors perform monitoring inspections to verify that State agencies are enforcing Federal requirements. Our Federal survey findings demonstrate a 98 percent correlation with State findings.

The survey process permits ongoing monitoring of laboratory compliance with standards to detect and correct deficiencies. Laboratories receive verbal and written notice of deficiencies and must submit a plan of correction for each deficiency. The State surveyors evaluate the laboratory's corrective efforts and the laboratory is terminated from the program if appropriate action has not been completed within 90 days of the survey.

One of the most important conditions of participation that has recently received a great deal of media attention, is proficiency testing. Both Medicare and CLIA require that laboratories participate in an approved program of proficiency testing. In some instances, States conduct proficiency testing programs; other approved programs are conducted by professional organizations such as the College of American Pathologists and the American Association of Bioanalysts.

Generally, proficiency testing is conducted on a quarterly basis with a shipment of one to three sample specimens in each testing category being sent to each laboratory. The evaluation of test results are sent to the laboratory and the State survey agency. Medicare considers three consecutive or three out of four consecutive unsuccessful proficiency testing results to constitute the basis for adverse action against a laboratory. If the laboratory is terminated from performing tests in a specialty or subspecialty area, it cannot be considered for reinstatement until successful performance has been achieved for two consecutive quarters of proficiency testing.

At present the proficiency testing programs cover bacteriology, mycology, parasitology, syphilis serology, other serology, routine chemistry, other chemistry, hematology, and immunohematology. However, a problem with these programs is that they vary broadly in proficiency testing criteria and in grading of test results. Moreover, at this time there are no uniform or minimally acceptable Federal standards for proficiency testing programs. Finally, there are some subspecialty areas where national proficiency testing programs do not exist, most notably in the area of cytology.

OBRA-87 gave the Department authority to impose intermediate sanctions on deficient laboratories, short of termination or precluding payment for categories of tests based on unsuccessful proficiency testing performance. These intermediate sanctions may include directed plans of correction, civil fines and penalties, payment for the cost of on-site monitoring and suspension of payments. We are now developing regulations on the circumstances under which various types of intermediate sanctions can be imposed and expect to implement them by the effective date of January 1, 1990.

A CLIA laboratory may be disciplined through licensure revocation or limiting the types of tests the laboratory can perform. However, before an adverse action can be taken to revoke, limit or suspend a license, the laboratory must be notified and given the opportunity for a hearing before an Administrative Law Judge.

Department Laboratory Initiative

Recent attention has again focused on the quality of testing services offered by the laboratory industry as a whole. Before I describe the Administration's initiatives to increase our emphasis on quality, I would like to place them in the context of the changing nature of the laboratory industry.

Advancing technologies have led to the automation of laboratory testing resulting in :

- the capacity simultaneously to run large numbers of tests with rapid turn-around times;
- changes in skills needed by technical personnel;
- increased precision and accuracy;
- decreased marginal costs per test; and
- the feasibility of performing many tests in physicians' offices.

The organization and ownership of laboratories have also changed as a result of advancing technologies. Once primarily non-profit and hospital-based, the laboratory industry has become one of profit-making independent and large commercial ventures. During this evolution, laboratories began competing for business by offering low prices to physicians, discounts for volumes, and shorter turn-around times.

It is within this context, that we have concluded that regulatory reform for clinical laboratories is necessary. As with other areas of the Medicare program, we believe it is appropriate to refine outcome measures of laboratory performance, and we have been working to develop standards that will meet our quality objectives.

By the end of April, we expect to propose comprehensive regulations which will enhance the three fundamental components that determine the quality of laboratory performance: proficiency testing, personnel qualifications, and quality assurance in laboratories. In general, the regulations will:

- improve outcome measures of performance;
- include the national criteria for unified proficiency testing to provide effective external monitoring of Medicare and CLIA laboratory performance;
- assure that personnel requirements in the regulations reflect the state-of-the-art in laboratory science;
- provide quality control requirements that are appropriate for the new technologies and methodologies used in labs today; and
- remove outdated, obsolete, and redundant requirements.

Because of the lack of consistency in proficiency testing programs, we asked the CDC to develop a uniform proficiency testing program, to be used as a national standard in evaluating the performance of Medicare and CLIA laboratories. In developing the proficiency testing program, the CDC consulted with professional groups, held public meetings to solicit comments and debate on proposals, and published a notice in the

Federal Register of March 31, 1987 to elicit further public comment. In December 1987, CDC submitted a proposal for our national uniform proficiency testing program, which we are considering as part of our proposed regulations.

There is also continuing public concern about the accuracy of cytology testing, particularly in the area of cervical cytology, and there is growing consensus among the scientific community that cytology test accuracy must be improved. There is considerably less consensus, however, about what changes should be made in current laboratory practice to achieve these needed improvements. Such issues were the subject of a CDC-sponsored meeting on March 1 and 2 of this year, a meeting designed to seek advice from a variety of governmental and nongovernmental scientists working in this area.

Secretary Bowen is also concerned about performance in the cytology area. We are sensitive to the attention that has been given to Pap screening. The Department is evaluating all options to help improve the accuracy of cytologic testing through measures such as proficiency testing, standards for training and qualifications of cytotechnologists, and internal quality control procedures to be applied by the laboratories themselves. We recognize that the accuracy of cytologic testing remains an extremely complex health care issue, and we are working to assure that any regulatory requirement or standard will be based on careful scientific assessment.

Before closing, I would like to address the topic of physician office laboratories. Congress has mandated a study of these laboratories to determine appropriate standards to protect the health and safety of patients. The report, which will be released soon, will address such factors as the scope, type and complexity of testing in physician office laboratories. We hope the report will provoke public debate and the emergence of sound public policy options that will assist us in developing regulations, as required by OBRA-87, for high volume physician office laboratories for implementation on January 1, 1990.

Conclusion

In conclusion, let me reinforce the Department's commitment to assure quality laboratory services not only for Medicare and Medicaid beneficiaries, but for all of our nation's citizens. The Medicare survey and certification process goes far to assure that quality standards are being met by the many thousands of laboratories throughout the country. However, we recognize that the rapidly changing clinical laboratory environment requires updated, reliable quality measures to assure the adequacy and accuracy of test results. We want to move quickly to put these measures into place and welcome your advice and the continued assistance of laboratory professionals in developing these reforms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
[illegible] GA 30333

FOR RELEASE ONLY UPON DELIVERY

TESTIMONY OF

PAUL J. WIESNER, M.D.

DIRECTOR

TRAINING AND LABORATORY PROGRAM OFFICE

CENTERS FOR DISEASE CONTROL

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
OF THE
COMMITTEE ON GOVERNMENTAL AFFAIRS

U.S. SENATE

March 24, 1988

Mr. Chairman and Members of the Subcommittee:

I am Dr. Paul J. Wiesner, Director of the Training and Laboratory Program Office, Centers for Disease Control, representing the Centers for Disease Control. Thank you for inviting us to present our views on the federal government's role in ensuring the quality of medical laboratory testing.

Introduction

Both this Committee and the Centers for Disease Control (CDC) share a strong commitment to a common goal--the continuing good health of the American people. Clinical laboratory testing can play a significant role in supporting that goal by aiding in early detection of treatable disease, identification of risk factors, and proper diagnosis in medical practice.

Since enactment of the 1967 Clinical Laboratories Improvement Act (CLIA), there have been substantial improvements in the performance of the Nation's clinical laboratories. Regulation of laboratories under CLIA and Medicare/Medicaid programs has contributed to these improvements, as have the educational and training programs of professional societies, private industry, and government entities. Sophisticated computer-based technological advances have brought the analytical accuracy of many test systems to very high levels. The Food and Drug Administration's (FDA) development and application of the Medical Device Amendment of 1976 has significantly influenced the quality of the instruments and materials available for laboratory testing.

To put our testimony into context, I emphasize that the actual laboratory analysis of a specimen is just one of several important steps in a total laboratory testing process. Laboratory testing must serve specific clinical or public health purposes. Therefore, the quality of the total testing process is critical--beginning with the decision to order a particular laboratory test and ending with the correct test interpretation and communication of results to the patient. To adequately address the issue of quality, we must be concerned with each step in this process:

- Selection of appropriate test
- Proper collection, labeling, transportation, and storage of specimens
- Application of appropriate techniques and methods
- Conducting the test in the laboratory
- Timely and accurate reporting of test results
- Accurate interpretation of results and application to patient health

To build on past accomplishments, we must develop a modern system for further improvement in laboratory testing. The world of laboratory medicine has changed dramatically in the past 20 years. Technology has revolutionized the volume of testing and the nature of testing systems. Laboratory testing has been dispersed to an ever-widening array of clients and users (from hospitals to home kits). The general population has become sophisticated in its understanding of medical decision-making and has the capacity to become even more so. In response to these changes, the Department is considering regulatory reform to implement more effective standards, eliminate obsolete provisions, and provide more efficient mechanisms for updating regulations as new scientific data become available.

CDC does not believe, however, that making changes in existing regulations is the only and sufficient answer to concerns about the quality of the laboratory testing process. We strongly advocate regulatory requirements for internal quality control and proficiency testing because they contribute directly to the quality of laboratory analyses. They do not, however, directly address all of the issues of the quality of laboratory testing. Many of these issues emanate from problems in collecting and preparing a specimen before it is analyzed and interpreting and using the results of the analysis. Epidemiologic and laboratory studies of the reasons for errors in the laboratory testing process are needed if we are to adequately serve public health. The real question should not be limited to "How well are laboratory analyses being done?" but rather "How well is the total laboratory testing process meeting clinical and public health needs?"

To help answer this question, CDC, State and local health departments, regulatory entities, professional organizations, and private industry are initiating studies focused on the quality of the total laboratory testing process. For example, CDC is using resources previously devoted to routine proficiency testing activities to develop a Model Performance Evaluation

Program to evaluate the quality and effectiveness of emerging laboratory technologies in support of health objectives. The National Ambulatory Medical Care Survey to be conducted by CDC's National Center for Health Statistics in January 1989 will solicit information from approximately 2500 physician office laboratories on procedures, personnel, and internal and external quality control measures.

The aim of such studies is to collect the baseline data necessary to develop methods to identify and resolve problems that exist in the total testing process. These and other needed studies will lead to more effective approaches to improving the quality of clinical laboratory performance.

With that overview, my remaining testimony will focus on five areas in which the Committee expressed particular interest:

(1) The role that the Centers for Disease Control now performs in assessing the quality of Medicare-certified and CLIA-licensed laboratories.

CDC has accepted a dual role in assessing the quality of the Nation's clinical laboratories. First, CDC provides technical support to assist the Health Care Financing Administration in meeting their regulatory responsibilities. Second, CDC conducts epidemiologic and laboratory studies to identify and resolve problems in clinical laboratory testing.

In October 1987, CDC and HCFA signed a new Memorandum of Understanding that reflects their respective roles in Federal regulatory and non-regulatory laboratory quality activities. Under the 1987 MOU, CDC is responsible for:

- Initiating scientific studies to identify trends in laboratory performance and services that may result in a need for new or modified regulatory procedures or guidelines.
- Providing or assisting HCFA in obtaining the technical and scientific expertise required to resolve issues raised by new technology, health care delivery modes, and changing laboratory service patterns.
- Developing uniform proficiency testing standards for CLIA '67 and Medicare laboratories.
- Assisting HCFA with technical issues related to determining the equivalency of State and other accrediting organization proficiency testing programs to HHS standards.
- Conducting studies pertaining to the technical and scientific aspects of health care delivery systems including quality control practices, data handling and reporting practices, evaluations of methodologies used in testing, trends in performance, and variables identified as indicators or predictors of good and unsatisfactory performance of laboratories and health care delivery systems.

In proficiency testing, for example, CDC provides assistance in three different areas. For new technology or testing just being introduced into the nation's clinical laboratories (the tests for HIV antibody being the most recent example) the CDC trains laboratory workers and develops and initiates proficiency testing. Once proficiency testing for new technologies and new tests is considered routine, the logistics can be effectively carried out by private sector programs.

The second category of CDC's work in proficiency testing addresses those tests that are not new but for which proficiency testing is technically difficult, such as the Pap smear for cervical cytology. For this category of tests, CDC works to develop new approaches to solve the technical problems with proficiency testing or to develop consensus on the most appropriate methodologies.

The third category of tests are those that are well established in clinical use and for which a vast experience in proficiency testing already exists. Proficiency testing for these tests is now efficiently conducted by the private sector. However, performance criteria are described in our proposed Uniform Proficiency Testing Program.

The CDC cooperates with regulatory entities, State and local health departments, professional organizations, and private industry to accomplish both the epidemiologic studies necessary to identify the reasons for errors in the total clinical laboratory testing process and needed regulatory reform .

(2) Your views on the need for a uniform proficiency testing program for Medicare-certified and CLIA-licensed laboratories and actions that the CDC is taking to develop such a program.

A uniform proficiency testing program would be useful. The Clinical Laboratories Improvement Act of 1967 authorizes the Secretary to require laboratories to participate in a proficiency testing program. Participation for Medicare-certified laboratories is required by regulation.

The wisdom of the proficiency testing requirement has been demonstrated by the widely recognized improvement in CLIA licensed lab performance over the past two decades. Without external feedback on the accuracy of its results, a laboratory is hard pressed to evaluate its instruments, methods, and technical competence. Improved accuracy has been documented among laboratories participating in proficiency testing programs. However, States and private organizations have offered or approved proficiency testing programs that vary considerably in their degree of challenge and performance criteria. Because of the lack of consistent standards among PT programs, HCFA asked CDC to describe a proficiency testing program that could be applied to federally monitored laboratories in a uniform manner.

CDC described a program that focused on assessing, when technically feasible, the quality of those laboratory tests whose results are widely used or, if in error, carry a moderate-to-high risk of death or severe injury to the patient. The CDC proposal contains general and specific requirements that a provider of a proficiency testing program must meet to qualify as an approved program provider in the areas of chemistry, hematology, immunohematology, and microbiology. Also included are proposed criteria for acceptable laboratory performance in each of these areas.

The major steps taken in developing this uniform proficiency testing program proposal for HCFA were as follows:

April 1987	A draft was distributed to State and Federal agencies, professional societies, and manufacturers for comment.
May 4, 1987	Following an announcement in the Federal Register, a public meeting was held at CDC to permit comment.
August 1987	Taking into account the comments received both at the meeting and subsequently, a revised version of the CDC proposal was circulated for comment.

December 1987	A final version of the CDC proposal was submitted to HCFA for consideration in the Department's regulatory package.

HCFA is considering incorporation of the CDC proposal into regulation. Proficiency testing in and of itself does not identify the reasons for poor laboratory performance, determine the extent of the problems, or provide the means of correction.

(3) Actions that CDC is taking to develop a PT program for cytology, focusing on (Papanicolaou) Pap smear test results.

The CDC has recognized for a number of years the importance of developing useful standards for cytology performance based on sound scientific principles. On March 1 and 2, CDC, the National Institutes of Health, and HCFA sponsored a conference to address quality control measures for diagnostic cytology. The conference brought together about 150 individuals representing a broad range of professional organizations as well as governmental entities involved with these concerns. The purpose of the conference was to discuss the important issues related to Pap smear screening and to have these individuals solicit comments on the subject at their organizational meetings. We will provide alternatives to HCFA to be considered for incorporation in a Notice of Proposed

Rulemaking. Thereafter, CDC will meet with representatives of the relevant societies to discuss standards for Pap smear screening, including cytology proficiency testing. Information from these activities, along with comment received in response to the Notice of Proposed Rulemaking, will be considered in developing any final standards.

The Pap smear poses a unique set of problems for controlling quality and evaluating performance. Generally, proficiency testing of laboratory procedures is accomplished by making large pools of blood or urine and dividing these pools into small samples for testing. Due to the nature of the Pap smear, it is not possible to create a pool from which to draw samples. There are, of course, other actions in addition to proficiency testing which can contribute to improved performance of Pap smear tests. Such measures include personnel standards for cytotechnologists, limitations on the number of cytology specimens reviewed by an individual cytologist in a given time period, internal review of a certain number of smears read as negative as well as smears read as suspicious or positive, and introduction of suspicious or positive smears into the daily work load.

(4) Any recommendations that the CDC has to improve the statutory or regulatory scheme governing Medicare-reimbursed or CLIA-licensed laboratories in order to improve the quality of test results in such laboratories.

A very important step in improving the statutory or regulatory scheme governing Medicare-reimbursed or CLIA-licensed laboratories is the leadership that HCFA has shown in proposing the regulatory package that is being considered by the Department. CDC continues to give high priority to its support of HCFA's regulatory agenda for the Nation's clinical laboratories. From a technical and scientific perspective, activities central to HCFA's balanced regulatory program are standards for internal quality control and quality assurance, and participation in proficiency testing. Documentation and inspections confirm compliance with these standards and form the basis for licensure or certification. CDC supports the ongoing efforts with HCFA to maintain an appropriate and modern regulatory program--a program that has made definite contributions to the quality of medical laboratory testing in the U.S.

There is also a strong need to undertake epidemiologic studies and demonstrations to identify and prevent costly laboratory errors and improve the overall quality of laboratory performance. Often the problem is not identifiable by the currently acceptable procedures for internal or external quality control. The anticipated rapid changes in the Nation's laboratory system require epidemiologic studies directed at the following:

1. Understanding the changing laboratory system in relation to public health objectives.
2. Detecting the barriers in the total testing process that, if overcome, could reduce morbidity and mortality, and improve the quality of life.
3. Developing intervention strategies to overcome such barriers.
4. Responding to the problems by sharing information or directly intervening when appropriate.

(5) The progress CDC has made in developing the Clinical Laboratory Information, Profile, and Reporting System (CLIPARS) and the anticipated utility of this data base in assessing laboratory quality issues.

The subject of CDC's 1986 Institute on Critical Issues in Health Laboratory Practice was Managing the Quality of Laboratory Test Results in a Changing Health Care Environment. At this working conference, about 120 representatives from the public and private sectors identified six functional areas in the total testing process as critical to the quality of the test result.

- Clinical Question
- Specimen Sampling Management
- Technology/Methodology
- Laboratory Analysis
- Results Validation/Reporting
- Application/Interpretation of Results

The Clinical Laboratory Information Profile and Reporting System (CLIPARS) was designed to address only two (Technology/Methodology and Laboratory Analysis) of the six functional areas identified by the Institute. In order to address issues relating to all six areas, CLIPARS has been replaced by a series of more focused data collection activities that will enhance our capability to identify problem areas within the total testing process.

As a follow-up to the 1986 Institute, demonstration activities are being developed that will allow the public and private sector to collaborate on identifying the information necessary to assess the effect of all six areas on the quality of the test result and the subsequent impact on patient health.

Data from private sector proficiency testing providers are currently being assembled and analyzed in accordance with the proposed uniform proficiency testing program. Selected descriptive and correlation analysis of this data will point to important trends in laboratory performance and testing that will identify analytical processes in need of intervention.

A Model Performance Evaluation Program is being developed to assess the quality of the testing process and measure the impact of the quality of testing on public health. This model program is being developed using HIV testing as a specific application.

These focused activities work together to provide a more comprehensive data base that addresses the total testing process:

1. The Institute demonstrations will identify the measurement tools necessary to assess problems in all six functional areas and describe the magnitude and extent of the adverse health effects associated with the quality of laboratory testing.
2. The private sector proficiency testing data and the uniform PT program will allow continued monitoring and enforcement of proposed regulations as well as identifying trends in performance.
3. The Model Performance Evaluation Program will implement data collection activities based on results of research contracts and Institute demonstrations directed at all six functional areas.

Conclusion

In summary, laboratory testing is a dynamic field. In the last twenty years the field of medicine has seen a tremendous growth in the number of tests performed, the number of different methods available for testing, and the movement of laboratory testing into the physician's office. The next twenty years will probably see comparable changes. A system to assure quality of laboratory testing must have the flexibility to adapt to changes in order to provide the best protection for the public. Standards of quality will change, as will the use of particular tests for particular purposes.

The questions we should be concerned with today are not only whether laboratories are using quality control procedures, whether they do proficiency testing or whether they are accredited. Of course they should, and they are. The critical question today is whether an individual laboratory test result provides the information that is necessary to meet clinical and public health needs.

Recent media discussions of laboratory testing have focused on a number of tragic cases in which death or inappropriate treatment was attributed to laboratory error. Unfortunately, we have no measure of how frequently these incidents occur, if they are limited to certain laboratories, or if they are widespread and occur frequently in approved laboratories. If we are to understand the causes of these incidents and develop appropriate interventions, we must have tools to determine where, how, and how frequently they occur.

As described earlier, the 1986 Institute on Critical Issues in Health Laboratory Practice identified six stages in the testing process that are critical to health care. In the physician's office, all of these stages may occur at one site and be the responsibility of the physician. In the hospital or independent laboratory, while all stages may be the general responsibility of either the clinician or the laboratory director, each stage may occur at a different site and involve numerous people. In either case, the quality of the test result depends on the successful transfer of quality through all six stages of the total testing process.

Currently, the regulation of clinical laboratories focuses on three of the six critical stages: The specimen/sampling management, the laboratory analysis, and the results validation/reporting. Of those three, only the laboratory analysis stage has data available, through proficiency testing, to evaluate the performance characteristics of the test and the laboratory performing the test. Proficiency testing, when conducted appropriately, provides meaningful outcome measures for the analytical process. However, outcome measures are needed for the total testing process that proficiency testing does not and cannot address.

Epidemiologic studies are needed to develop the data bases necessary to establish quality standards and to measure their effectiveness in improving the quality of the total testing process. It has become increasingly apparent in recent years that epidemiologic studies and development activities need to be conducted that will:

- Identify the magnitude and extent of the health problems associated with the testing process

- Identify testing problems critical to health
- Trace the source of problems (methodology, practice, sampling, lack of quality control, lack of training, etc.)
- Develop corrective strategies
- Demonstrate effectiveness of various corrective interventions
- Develop better measurement tools for finding and tracing problems
- Develop and implement training, consultation, and technical assistance programs based on improvement needs
- Develop standards of practice to be used in voluntary or regulatory mode as required
- Assess the effectiveness of standards

HCFA, FDA, and CDC all have a role in assuring that our nation's laboratories provide quality results. HCFA regulates the laboratories, and FDA regulates the products used in the laboratories. CDC's role is to develop new methods to assess the quality of laboratory testing, to evaluate the effectiveness of various interventions, and to assist the regulatory agencies in developing standards as indicated by the data. We believe it is possible for Federal, State, and private organizations to collaborate effectively to develop a system of laboratory testing support that is based on requirements of the users, the clinicians and their patients. This system would assist laboratories in efficiently and effectively carrying out their responsibilities and would have the flexibility to be responsive to changes as they occur.

This concludes my testimony. I will be glad to answer any questions.

STATEMENT
OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS
ON THE FEDERAL GOVERNMENT'S ROLE
IN ENSURING THE QUALITY OF MEDICAL LABORATORY TESTING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT

SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS

March 24, 1988

Mr. Chairman, I am Dennis S. O'Leary, M.D., President of the Joint Commission on Accreditation of Healthcare Organizations. With me today are Mr. Clifford Houser, Associate Director for Medical Technology, of our Hospital Accreditation Program and Mr. Paul Mullen, our Director of Government Relations. I am pleased to have the opportunity to present the views of the Joint Commission on the federal government's role in ensuring the quality of medical laboratory testing. Considering the historic roles of the Joint Commission in the area of quality assurance and as a component of the Medicare/Medicaid hospital certification system, we believe it particularly appropriate that our views on this issue be included in the record of these proceedings.

HISTORICAL BACKGROUND

Before addressing myself to the subject of these hearings, I would like to present background information about the Joint Commission. The Joint Commission's voluntary hospital accreditation program originated through the American College of Surgeons (ACS). The College members believed that a system of standardization of hospitals and hospital work should be developed and in 1915 they allocated $500 to establish standards for promoting high-quality patient care in hospitals. By 1917, with the financial assistance of the Carnegie Foundation, the ACS had compiled a list of requirements called the Minimum Standard for Hospitals.

In 1918 the ACS instituted a program to conduct on-site inspections of hospitals having more than 100 beds. In the first year the program was offered, almost 700 hospitals were inspected, but only 89 met the requirements of the Minimum Standard. These statistics, which the ACS released without naming the hospitals that had been inspected, made the American medical community keenly aware of the need for the ACS standards. With the support of the medical community, ACS Accreditation became a widely accepted means of maintaining and improving the quality of care. By 1951 voluntary Accreditation had proved its value to the health care field; more than 3,000 hospitals had been voluntarily surveyed and had met the Minimum Standard.

The success of the hospital standardization program made it impossible for the ACS to continue to support it alone, and other national professional organizations were invited to participate. Thus, in 1951, the American College of Physicians, the American Medical Association, the Canadian Medical Association and the American Hospital Association joined with the ACS to form the Joint Commission on Accreditation of Hospitals. The Canadian Medical Association withdrew to form its own national accrediting organization in 1959, and the American Dental Association joined the Joint Commission in 1980. Through the years, the member organizations have helped shape Joint Commission policy through their representatives on the Board of Commissioners, the Joint Commission's governing body.

Today, the Joint Commission is governed by 22 commissioners, 21 of whom are appointed by the five member organizations. In 1981 the Board of Commissioners appointed a public member to provide the perspective of the broader community of interests.

The Board meets three times a year to examine current issues relating to the standards and survey process for the Joint Commission's six accreditation programs: The Accreditation Program for Ambulatory Health Care, the Accreditation Program for Home Care, the Accreditation Program for Hospice Care, the Hospital Accreditation Program, the Accreditation Program for Long Term Care, and the Accreditation Program for Psychiatric Facilities.

Data with respect to these programs follow.

Accreditation Program for Ambulatory Health Care. The following types of ambulatory health care organizations and programs are eligible for accreditation by the Joint Commission:

- Ambulatory surgery centers;
- Armed services clinics;
- College and university health programs;
- Community health centers;
- Emergency care centers;
- Family practice centers;
- Health maintenance organizations;
- Multispecialty group practices;
- Primary care centers;
- Single-specialty group practices; and
- Urgent care centers.

Approximately 445 programs are currently accredited.

Accreditation Program for Home Care. In 1986 the Joint Commission embarked upon an initiative to establish a separate accreditation program in this area. This action was taken in response to the rapidly growing home care services industry. Home care has become a viable, cost-effective alternative to hospitalization or other institutionalization, particularly for the elderly. Cost-containment pressures in inpatient care encourage the prompt discharge of patients whose needs for continuing care may be met in other settings, such as the home; and technological advances have made it possible to provide a greater variety of treatments in patient's homes. The increased attention to home care has prompted concern about the quality of home care services, which together with the concerns raised by payers, community-based home care providers, and other health care professionals, have indicated a need for national standards. The comprehensive standards and survey process developed through the Joint Commission's project will apply to all types of organizations providing home care services, including hospital-based agencies, proprietary agencies, and community non-profit agencies. The accreditation process for home care services will become available in June 1988.

Accreditation Program for Hospice Care. The Accreditation program for Hospice Care was established to encourage the provision of high-quality care for terminally ill patients and their families. The Joint Commission surveys and accredits all types of hospice care providers, including

. independent programs;
. hospital-based programs;
. programs that are a service of a home health agency;
. programs that are a service of a long term care organization; and
. programs that are a service of a psychiatric organization.

To be eligible for survey, a hospice program must offer interdisciplinary team services at home and in inpatient settings. Interdisciplinary team services include physician, nursing, psychological/social work, spiritual, and bereavement services. Hospice programs are surveyed with the Hospice Standards Manual.

The Accreditation Program for Hospice Care was established in 1983 after an extensive 2 1/2-year study of hospice organizations in the United States. With funding from the WK Kellogg Foundation of Battle Creek, Michigan, the Joint Commission initiated the study in recognition of the growing importance of hospice care. During the project, standards and self-assessment and survey processes for hospice programs were developed, and in January 1984, the nation first accreditation program for hospice care began conducting surveys.

Approximately 347 hospice programs are currently accredited.

Accreditation Program for Long Term Care. The Accreditation Program for Long Term Care originated in the 1960s and is the Joint Commission's second oldest accreditation program. The program surveys both hospital-based and freestanding long term care organizations. More than 1,300 long term care organizations are currently accredited under the Long Term Care Standards Manual.

Accreditation Program for Psychiatric Facilities. The Joint Commission established the Accreditation Program for Psychiatric Facilities to encourage the provision of high-quality care for patients and residents of psychiatric and/or substance abuse organizations and programs. These programs and services include

- alcoholism and substance abuse programs;
- community mental health service programs;
- forensic psychiatric services;
- programs for the mentally retarded/developmentally disabled; and
- psychiatric services.

The Joint Commission currently accredits more than 1,200 facilities, programs, and services under the Consolidated Standards Manual.

Hospital Accreditation Program. The Hospital Accreditation program accredits all types of general hospitals under the nationally recognized standards in the Accreditation Manual for Hospitals. Approximately 5,000 of the nation's 5,800 general hospitals are accredited. Hospital-based psychiatric and substance abuse services and freestanding psychiatric and substance abuse hospitals are also surveyed and accredited through the Hospital Accreditation Program.

Each accreditation program is advised by a Professional and Technical Advisory Committee (PTAC) composed of experts in the field. Most PTAC members represent health care professional organizations active in their respective fields. The knowledge and experience of PTAC members help to ensure that the accreditation programs address current health care trends. Accreditation program and standards development staff work closely with the PTACs in establishing and refining standards and in strengthening the survey process.

In 1986 the Joint Commission adopted an "Agenda for Change" to seek a more refined approach to the evaluation of the quality of care. While the accreditation process traditionally has focused on the structure and process of heath care delivery, the Agenda for Change calls for the development of measurements of clinical and organizational performance. In addition, standards are being developed to address the issue of undercare and the importance of risk management activities, especially with regard to patient safety and quality assurance.

In recognition of the expanding array of health care programs participating in the accreditation process the Board of Commissioners acted, in 1987, to redesignate the organization the Joint Commission on Accreditation of Healthcare Organizations.

QUALITY OF MEDICAL LABORATORY TESTING

You have asked that the Joint Commission provide your subcommittee with views focusing on four broad areas. This information follows.

The Joint Commission Hospital Accreditation Process

As noted above the Joint Commission accredits 5,198 hospitals which either operate an integral clinical laboratory, obtain such services under arrangement or provide such services through a combination of the foregoing. In brief, the accreditation process may be outlined as follows:

- establishment of hospital accreditation standards, including standards for clinical laboratories;

- differentiation between standards of critical importance to accreditation and those of somewhat less importance;

- establishment of criteria for scoring standards compliance;

- training of hospital accreditation program surveyors ...the basic hospital accreditation survey team includes

    - a physician (with experience as chief of a hospital medical staff),

    - a nurse (masters degree with experience as a hospital nurse administrator),

    - a hospital administrator (masters degree with experience as a hospital chief executive officer), and

    - a medical laboratory technologist (certified medical laboratory technologist; nearly all Joint Commission laboratory surveyors are educated at the masters degree level and many at the PhD level) ...a laboratory technologist surveyor is not a survey team member if all of a hospital's laboratories are accredited by the College of American Pathologists;

- conduct of accreditation surveys of applicant hospitals by survey teams;

- report of survey findings to the Joint Commission central office for analysis, review and validation;

- presentation of survey findings to the Accreditation Committee of the Joint Commission Board of Commissioners;

- rendering of an accreditation decision by the Accreditation Committee, which may include,

  - unencumbered accreditation,

  - accreditation with contingency(ies)--the hospital is advised that its affirmative accreditation is contingent upon correction of one or more significant problems within specified times, or

  - nonaccreditation;

- rendering of an accreditation report advising the hospital of the accreditation decision; and

- if applicable, monitoring of problem resolution by the hospital.

Relationship Between the Joint Commission and the Health Care Financing Administration (HCFA)

Section 1865 of the Social Security Act as implemented through 42 CFR 405.1901 provides that hospitals accredited by the Joint Commission shall be deemed to meet the health and safety standards requisite to Medicare participation.

Sections 244, PL 92-603, the Social Security Amendments of 1972 established a requirement for Department of Health and Human Services oversight of hospitals participating in Medicare through the Joint Commission accreditation process. This oversight involves the HCFA inspection of an annual random sample of accredited hospitals and the conduct of complaint investigations of such hospitals and an annual report to Congress concerning the outcome of these inspections. This may be characterized as an annual governmental assessment as to whether accredited hospitals meet Medicare's hospital health and safety standards and, based on these findings, a conclusion concerning the prudence of continuing governmental reliance on accreditation for Medicare certification purposes.

Since 1973 when validation surveys were first inaugurated, the following Joint Commission-HCFA arrangements have evolved:

- the Joint Commission provides HCFA with schedules of contemplated hospital accreditation surveys;
- the Joint Commission provides HCFA with the results of the deliberations of its Accreditation Committee with respect to hospitals i.e., accreditation or nonaccreditation; and
- the Joint Commission provides HCFA with copies of accreditation reports respecting hospitals subjected to HCFA validation and complaint inspections.

The Joint Commission has no relationship with HCFA respecting clinical laboratories involved in interstate commerce. It is of course likely that from time to time an accredited hospital operating a clinical laboratory in interstate commerce is selected for a Medicare validation or complaint inspection and in such cases the Joint Commission would provide HCFA a copy of the hospital's accreditation report including comments pertinent to the clinical laboratory.

Statistical Data Re Clinical Laboratory Problems in Accredited Hospitals

Practically all hospitals which participate in the accreditation process receive recommendations for clinical laboratory improvement. In 1986 the Joint Commission laboratory technologist surveyor participated in 893 hospital accreditation surveys. Approximately 11% of the accreditation decisions pertinent to these surveys resulted in a contingency being attached to the hospital's accreditation respecting the clinical laboratory, i.e., continued accreditation was contingent upon clinical laboratory problem correction within specified time-frames. In more than half of these instances the Joint Commission required on-site verification of problem correction.

In 1987 the Joint Commission laboratory technologist surveyor participated in 716 hospital accreditation surveys. Approximately 15% of the resultant accreditation decisions involved a clinical laboratory contingency. Detailed data follow:

Hospital Accreditation Contingencies
Arising from
the Clinical Laboratory Component of the Joint Commission Survey

(893 Surveys)

1986

Generic Problems	Contingency - Numbers of Decisions			
	Contingency Report		Contingency Visit	
	No.	Percent	No.	Percent
Laboratory Proficiency Testing	20	41	11	22
Quality Control	16	33	15	29
Administrative Procedures	7	14	12	23
Safety	4	8	7	14
Professional Staff	2	4	6	12
Total	49	100	51	100
Percent of Surveys Yielding Contingency	5.5%		5.7%	
	(716 Surveys)			
	1987			
Laboratory Proficiency Testing	27	42	11	28
Quality Control	17	27	14	35
Administrative Procedures	9	14	10	25
Safety	6	9	3	7
Professional Staff	5	8	2	5
Total	64	100	40	100
Percent of Surveys Yielding Contingency	8.9%		5.6%	

Federal Government Role in Enhancing the Quality of Clinical Laboratory Testing

From the point of view of the Joint Commission, the major issue respecting hospital quality assurance (including integral clinical laboratory quality assurance) is consistent failure to follow up on identified quality problems to prevent recurrence. Another major problem is the lack of sophisticated tools for identifying problems.

If we are to achieve significant progress in clinical laboratory quality improvement, there is a need for well-researched, scientifically sound, external evaluation systems for this functional area. There is no evidence that such systems presently exist or that any endeavors in this area are underway. We would further observe that the rapid advances in clinical laboratory instrumentation dictate an ongoing research initiative in this arena, for what may be an acceptable level of performance today will most certainly be unacceptable tomorrow.

In our view the first priority of government should be to underwrite a research effort designed to yield an external evaluation system for clinical laboratories. This is no small task. It is certainly a task beyond the financial capability of the hospital industry and one which would seem to embody no obvious incentives for the private sector.

The clear issue is whether increased federal regulation of clinical laboratories at the present time will yield significant quality improvements. We suggest:

- there is no national consensus on the definition of high quality clinical laboratory testing;

- there are no recognized systems for valid external evaluation of clinical laboratories;

- clinical laboratories which fail to meet the needs of the professionals using them will enjoy a very limited life cycle; and

- there seems to be little practical benefit of a more pervasive federal regulatory presence in the clinical laboratory arena at this time

We suggest a significant federal commitment to research in the area of external evaluation of clinical laboratory performance. The result of such an endeavor would clearly be of inestimable and immediate value to existing federal oversight of clinical laboratories, state agencies involved in this function, and private sector evaluations. Sophisticated tools in this arena may argue for an increased federal role in the future but more likely suggest the possibility of a decreased federal presence.

CLOSE

Thank you for providing me the opportunity and privilege of presenting the views of the Joint Commission on this important matter.

STATEMENT OF THE
COLLEGE OF AMERICAN PATHOLOGISTS
TO THE
SUBCOMMITTEE ON
OVERSIGHT OF GOVERNMENT MANAGEMENT
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

MARCH 24, 1988

Presented by:

Loyd R. Wagner, MD
Vice President
College of American Pathologists
Skokie, Illinois

CAP LABORATORY IMPROVEMENT PROGRAMS

The College of American Pathologists is a national medical specialty society representing more than 10,500 physicians who are certified, or are eligible to be certified, by the American Board of Pathology. Members of the College practice their specialty in community hospitals, medical schools and teaching hospitals, independent medical laboratories, and medical examiner/coroner offices.

Since it was established in 1947, the College has been dedicated to the pursuit of excellence in all areas of the medical laboratory. The purpose of this dedication has been to strive continually to improve the availability of quality laboratory services to the American public.

It is important that the Committee recognize that, prior to 1950, there was little availability of quality control materials and programs for the clinical laboratory to use in measurement of performance. The process of developing quality assurance methods for the protection of patients has been evolutionary. The methods available today are the result of a continuing effort by the College and other concerned organizations, governmental and private, to assure quality.

The College believes that the approach to quality assurance must be multi-faceted. Quality assurance cannot be measured by a single factor. Our view is that the College has attempted to bring together a variety of factors--inspection and accreditation, interlaboratory comparison, quality control, and standards to assess and compare the performance of one laboratory with another. Our opinion is that you cannot take a single factor in a total program and use it alone to measure how well or poorly a laboratory is performing.

During a 40-year period, the College has had more impact than any other single organization on standardization and improvement of clinical laboratory procedures. Frequently during this period, the CAP has worked on a collaborative basis with federal and private sector organizations to realize this achievement.

Through its Laboratory Improvement Programs, the College offers challenging, cost-effective programs that are carefully designed to help laboratories provide quality patient care. Examples of these programs and the scope of this service commitment to the laboratory community include:

(1) The CAP-Certified Reference Materials and Standard Solutions Program--Through its relationships with the National Bureau of Standards (NBS) and other national and international standards organizations, this program is rapidly becoming the laboratory community's primary source for standards used to ensure test accuracy.

(2) The CAP Surveys Program--Now serving 12,000 laboratories through interlaboratory comparison of test results on unknown, simulated patient samples, the CAP Surveys Program has been the largest and most comprehensive proficiency testing program available for more than 25 years.

(3) The CAP EXCEL Program--The CAP External Comparative Evaluation for Laboratories (EXCEL) Program provides proficiency testing for 2,000 physician office laboratories and other small laboratories.

(4) The CAP Performance Improvement Program (PIP)--This educational, peer review program provides patient diagnostic case material for individual study with followup educational critiques in anatomic and cervical pathology to 800 laboratories and 2,000 pathologists.

(5) The CAP Laboratory Accreditation Program (LAP)--Currently accrediting 4,000 laboratories through a rigorous inspection process, this program is widely recognized as the laboratory community's premier accreditation program.

(6) The Forensic Urine Drug Testing (FUDT) Program--Initiated in 1987 to meet the unique needs of laboratories performing forensic urine drug testing (FUDT) and emulating the National Institute on Drug Abuse (NIDA) Standards, the Forensic Urine Drug Testing Program provides specialized proficiency testing for approximately 200 laboratories performing FUD confirmation testing and 150 laboratories performing FUD screening testing. The program is cosponsored by the CAP and the American Association for Clinical Chemistry.

The College anticipates that many of these laboratories will seek accreditation in the CAP Forensic Urine Drug Testing Accreditation program, which will begin inspecting laboratories this year.

(7) The CAP Quality Assurance Service (QAS) Program--This peer review, daily quality control program serves 1,900 laboratories and is the only interlaboratory comparison program for daily quality control data which covers all medical laboratory disciplines and accepts data regardless of which vendor provides the quality control materials.

(8) The Commission on Office Laboratory Assessment (COLA)--The College, the American Society for Internal Medicine (ASIM), and the American Academy for Family Physicians (AAFP) are cosponsoring development of a model accreditation program for physicians' office laboratories.

To put the scope of these activities in perspective, it is useful to know that an estimated 3.4 billion laboratory tests were performed in the United States during 1987, including 2.5 billion tests in hospital laboratories, 336 million tests in commercial laboratories, and 529 million tests in physician office laboratories.

The College estimates that a minimum of 15 percent of a hospital laboratory's direct costs are consumed by quality assurance activities. A recent cost-accounting study at a 400-bed midwest hospital revealed that 20 percent of the laboratory's annual costs were assigned to quality assurance activities.

In the following sections, as well as through the attachments, information will be presented regarding CAP Laboratory Improvement Programs which have been at the vanguard of quality assurance in medical care. In most cases they have preceded federal regulatory initiatives.

CAP-Certified Reference Materials and Standard Solutions Program

The CAP began its laboratory improvement efforts with the introduction of the CAP Standards program in 1951. Prior to that time, few sources existed for clinical laboratory standards. This program became the only source for readily available and reliable calibration standards.

In 1957, the CAP initiated a certification program for cyanmethemoglobin standards in response to a request from the National Research Council of the National Academy of Science. These activities continue today in the CAP operation of the U.S. certification program for cyanmethemoglobin under the auspices of the standards issued by the International Committee for Standardization of Hemoglobin.

When the National Bureau of Standards (NBS) began a program to develop standard reference materials (SRM) in 1968, the CAP Cholesterol Standard Solution became the first clinical standard solution with its accuracy traceable to the NBS material. Prior to the advent of SRMs, CAP Standard Solutions were traceable to inorganic chemical standard reference materials. Since SRMs have been available, the CAP has provided traceability from its standards to the NBS SRMs in almost every instance where comparable NBS materials are available.

Throughout the 1970s, the CAP worked closely with the NBS on development of definitive methods for clinically important organic analytes. Comparison of proficiency testing results among laboratories were then correlated to definitive methods values.

In 1978, the CAP initiated the Roger K. Gilbert Research Associate Program at the NBS to expand on these efforts. After 10 years of supporting a doctoral scientist in this capacity at the NBS, the CAP in 1987 expanded this commitment at an annual cost of more than $100,000 by establishing a Standards Laboratory at the NBS. The CAP-Certified Reference Material for Cholesterol with analysis values assigned both by definitive method at NBS and by the Abel Kendall Reference Method at the Centers for Disease Control is an example of the returns from this commitment. Its use today assists laboratories in meeting the new cholesterol testing accuracy criteria advocated by the Lipid Research Clinics and the National Institutes for Health (NIH) Cholesterol Education Panel.

Other CAP-Certified Reference Materials are available for Alpha-fetoprotein, Chemistry, Factor VIII, Rubella IgG Antibody, and Serum Proteins. Aqueous-based CAP-Certified Standard Solutions are available for Alcohol, Calcium, Chloride, Glucose, and Protein. In 1988, the CAP/NBS collaboration also will result in additional CAP-Certified Reference Materials for cocaine, marijuana, and HIV (AIDS) antibody.

As this program expands, the CAP Standards Laboratory at the NBS will serve as an assay laboratory for most of the CAP-Certified Reference Materials. In addition to analysis by the NBS, CAP-Certified Reference Materials are assayed by federal agencies, such as CDC, as well as by numerous hospital, independent and manufacturer laboratories recognized for their special expertise with given analytes.

New reference materials developed by the College are submitted through the National Reference System for Clinical Laboratories (NRSCL) for certification as U.S. National Standards. In 1987, the CAP-Certified Reference Material for Rubella became the first rubella reference material to be designated as a U.S. National Standard.

The College maintains other ties to national and international standards-setting organizations. As a founding member of the National Committee for Clinical Laboratory Standards (NCCLS), the CAP is active in development and promulgation of performance standards. For example, data collected by the Microbiology Resource Committee through the CAP Surveys program was used to scientifically refute the necessity for intralaboratory repetition of manufacturers' media quality control checks, thereby eliminating an outdated 20-year-old federal performance standard and saving thousands of health care dollars annually. The CAP also serves as the Secretariat for the Commission on World Standards (COWS) of the World Association of Societies of Pathology (WASP).

Through its cooperative relationships with the NBS and other national and international standards-setting organizations, the CAP-Certified Reference Materials and Standard Solutions Program allows all laboratories to correlate their analysis values with the most accurate methods known to science today-- definitive methods which often require many months and thousands of dollars to obtain a single test result. When considering the importance of the accuracy for clinical laboratory procedures, the College is providing responsible leadership through development of these standards.

(See Attachment 1 for sample articles from medical literature regarding development, use, and effectiveness of CAP-Certified Reference Materials and Standard Solutions.)

CAP Surveys

The College's proficiency testing activities through interlaboratory comparison started in 1949 with an informal exchange of patient samples among several CAP members. This small, informal program was the precursor to the Surveys-type programs which were available nationally by the mid-1960s. Since then, the programs have expanded from a small group of tests to include most procedures commonly performed in clinical laboratories.

The CAP Surveys have become widely recognized by both government agencies and independent laboratories as a valuable means of monitoring and improving laboratory performance. Soon after the Clinical Laboratory Improvement Act (CLIA) of 1967 was passed, the combination of CAP Surveys and the CAP Laboratory Accreditation Program became the only program (other than the New York State program) accepted as equivalent to the federally-mandated program. This equivalency still exists today.

As state licensure programs and the Medicare program for hospitals and independent laboratories evolved, the CAP Surveys generally were accepted as meeting proficiency testing standards where the level and scope of the service offered was commensurate with the program selected. Virtually every state and U.S. territory (except New York State) which has clinical laboratory proficiency testing requirements accepts one or more of the CAP Surveys for meeting local requirements. Several provinces in Canada also require participation in CAP Surveys for meeting their provincial requirements. Additionally, CAP Surveys are shipped to a number of foreign countries, with the largest effort being a jointly-sponsored program between the Japanese Society of Clinical Pathologists and the CAP.

Except in rare instances where commercial technology is unavailable and services of research facilities must be obtained, CAP Surveys specimens are prepared to meet carefully constructed CAP specifications by well-known diagnostic manufacturers. These manufactures are required to adhere to Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) established by the Federal Drug Administration (FDA). This is in contrast to most state and former federal programs in which many specimens were prepared in public health laboratory environments without any requirements for meeting FDA GMP requirements. Specimen validity is certified by quality assurance steps in the manufacturing process, through referee and/or reference laboratory examination when needed, and by rigorous review of the interlaboratory comparison data by the Resource Committees of the CAP.

Specifications for the CAP Surveys specimens are established by the members of CAP Resource committees. Sixteen resource committees and subcommittees comprised of more than 100 MD and PhD experts design and monitor the programs to ensure continued relevance for the desired laboratory improvement goals. These committees meet from two to four times annually to review the status of the programs, recommend modifications, and establish evaluation criteria for participant performance. They also present national conferences relating to the state of the art in the various laboratory disciplines and publish reports relating to information obtained through the interlaboratory comparison programs. Selected from the leading experts within each medical discipline, no comparable cadre of scientific expertise has ever been amassed to provide regular review and input to a proficiency testing service. (A bibliography of conference proceedings and related articles is included in Attachment 1.)

Frequently, educational critiques are developed by the Resource committees discussing the state of the art for the particular analytes within the individual Survey. These critiques may relate to observed problems in performance, or provide a reference list whereby participants can obtain additional information about the analytes included in the Survey. In all cases, participants have the opportunity to correspond with the members of the resource committees to discuss performance problems and to seek counsel.

No other interlaboratory comparison program in the world approximates the volume or range of services, or has maintained the magnitude of expansion of programs to meet newly evolving technology.

From the initial concept through pilot testing to delivery of the first specimens of a new Survey, the time lapse is generally from 18 months to two years. Yet five to 10 new Surveys are added annually. (For a complete list of available CAP Surveys, see the 1988 CAP Surveys notebook. The growth history in number of participants and in expansion of available CAP Surveys since 1974 appears in Attachment 2.)

In 1988, 72 different CAP Surveys offering more than 300 analytes/organisms for analysis and/or identification are provided to approximately 12,000 clinical laboratory subscribers. In addition, the CAP Surveys for physician office laboratories provide more than 30 options for 3,000 subscribers. In total, more than 290,000 kits in 270 shipment dates are provided annually to some 69,000 subscribers, and more than 1.5 million clinically-simulated specimens are provided, with multiple challenges offered in most samples.

The CAP Surveys can be divided into four broad classes:

(1) The Comprehensive Surveys -- Surveys in Chemistry, Hematology/Coagulation, Immunohematology, and Microbiology, which provide a core group of interlaboratory comparison programs suitable for meeting the primary disciplines available in most clinical laboratories.

(2) The Specialty Surveys -- A group of 66 Surveys which allow laboratories to add subspecialty programs of increasing complexity and challenge to augment the analytes included in the comprehensive or core programs.

(3) The Basic Survey--primarily designed for more traditional small independent and small hospital laboratories which provide limited testing in several disciplines.

(4) The External Comparative Evaluation for Laboratories (EXCEL) Program--a modular array of small groups of analytes which allows physicians offices and very small independent laboratories to tailor a Survey program to meet their specific practice needs.

Although required for laboratories participating in the CAP Laboratory Accreditation Program (LAP) pursuant to equivalency agreements under CLIA 1967 and Medicare as administered by the Health Care Financing Administration (HCFA), CAP Surveys are available to any laboratory desiring to participate. Approximately 4,000 laboratories participate in these programs to meet CAP's LAP criteria which require that laboratories participate in CAP Surveys commensurate with the scope of testing being performed in that laboratory. Approximately 8,000 additional laboratories participate either on a voluntary basis or to meet other regulatory requirements. Approximately 1,300 laboratories composed primarily of physician offices also participate in the American Society of Internal Medicine's Medical Laboratory Evaluation program (ASIM/MLE), which is a mirror image of the CAP EXCEL Program.

For laboratories using participation to meet regulatory requirements, a copy of each evaluation report is provided by the CAP to the designated regulatory authority, upon authorization by the participant. Thousands of these reports are provided to state and federal agencies annually. Examples of these reports appear in the CAP Surveys manuals included in the 1988 CAP Surveys notebook. The CDC, acting on behalf of HCFA, receives from the College magnetic computer tapes of results from participants using such results for meeting CLIA and Medicare requirements. Summary reports of participant results are provided to each state monitoring agency requesting them.

Contrary to indications reported in recent GAO studies, CAP believes that many states do, in fact, use CAP and other proficiency testing programs data for monitoring laboratory performance and initiating intervention activities where appropriate. Although several states do not have state licensure programs, CAP believes most states act as primary enforcement agents of medicare regulations for HCFA. In other instances, agents review laboratories in the state directly out of the HCFA regional offices.

The CAP works with regulatory authorities wherever practical to assist them in meeting their regulatory missions as they relate to laboratory improvement programs. Complimentary participation is provided to several state agencies which either cannot afford the price of participation or which desire to receive the programs to monitor their equivalency to local standards. Similar subscriptions are provided to the CDC, which monitors CAP equivalency under CLIA and Medicare.

The CAP's cooperation with these agencies extends beyond the mere provision of data relating to participant performance. For many years, the CAP has maintained a CAP/CDC/HCFA Working Committee which meets with representatives of the federal agencies to review operations under the equivalency relationships, to evaluate changes in technology which affect regulatory monitoring programs, and to provide expert professional and technical consultation on areas of concern to the laboratory community. These forums have resulted in development of scientific studies and sharing of information which have assisted in altering obsolete standards and/or increasing the efficiency of the monitoring process.

For example, several years ago the CAP in collaboration with the CDC conducted a study comparing the extent of deficiencies observed between CAP laboratories in one year and two year accreditation cycles. The results of this study indicated that after the initial accreditation, no significant differences were observed between laboratories being reviewed at one year intervals vs two year intervals. This resulted in a policy change allowing CLIA laboratories meeting certain criteria to inspected at less frequent intervals thereby conserving valuable private sector, federal, and laboratory resources without decreasing the effectiveness of the regulatory system.

The CAP Microbiology Resource Committee through the Surveys Program collected extensive information regarding the effectiveness of individual laboratory performance of quality control testing of commercially prepared media. Through collaboration with NCCLS, a new performance standard Quality Assurance for Commercially Prepared Microbiology Culture Media (NCCLS Document M22-T) was developed which has resulted in elimination of redundant quality control testing for several types of media. This precipitated a change in federal requirements which has resulted in savings of hundreds of thousands of health care dollars annually. The Microbiology Committee is now reviewing other media requirements with aspirations of effecting other similar changes in future years.

In November of 1987 CAP provided data to a Congressional committee interested in assessing the quality of HIV antibody (AIDS) testing. Unfortunately extractions of an OTA study performed on this data were taken out of context and presented to Congress and the press reflecting severe accuracy problems in this procedure. In order to insure a factual reflection of the current state of the art in HIV testing, representatives of the CAP and CDC rapidly convened a task force which conducted an exhaustive review of the CAP data base and published the findings in the January 8, 1988 CDC Morbidity and Mortality Weekly Report dispelling the myths created by the previous publication and providing the basis for reinstillation of public confidence in this very important procedure.

During the past 18 months, the CAP has worked closely with the CDC in testing the potential effects on real participant data of proposals for the "Minimum Uniform Proficiency Testing Proposal" which was recently submitted to HCFA for inclusion in the developing "Conditions for Participation in Medicare." Encompassing more than 1200 hours of CAP staff and computer analysis time and at a cost in excess of $30,000, these efforts were extended to aid the federal government in establishing fair and equitable criteria which would insure that regulatory mandates were met while not creating an unrealistic set of criteria which would encumber the regulatory enforcement and appeals system for years to come. These are only examples of a few of the many instances where CAP and various federal agencies have worked together using CAP expertise and data to address problems and issues important to the laboratory and regulatory communities.

The CAP also cooperates with other professional associations which share common goals for laboratory improvement. For 1988, three Surveys are cosponsored with the American Association of Blood Banks (AABB), two are cosponsored with the Society for Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), two with the American Society for Histocompatibility Testing and Immunogenetics (ASHI), and five with the American Association for Clinical Chemistry (AACC).

A review of mechanisms and utility of proficiency testing will appear in the April, 1988 issue of Archives of Pathology and Laboratory Medicine. The text summarizes proceedings of the 1987 CAP national conference, "The Evaluation of Proficiency Testing Results for Quantitative Methods in Relation to Clinical Usefulness," which discussed the strengths and weaknesses of proficiency testing programs as a measurement of laboratory performance. Copies can be provided when available in April. We also have submitted a copy of proceedings from the 1986 benchmark CAP conference, "Quality Assurance in Physician Office, Bedside and Home Testing."

CAP Grading Criteria: Overview

All CAP grading criteria are designed to evaluate the quality of individual results on Survey specimens. Procedures for determining target values and the rationale for the various criteria are summarized below, and are described in detail in the following section, "CAP Grading Criteria: Rationale and Background". Further details on why some proficiency testing practices are used rather than others is discussed in the section "CAP Grading Criteria: Response to the 1981 Report of the Inspector General".

The CAP criteria can be summarized by the following two objectives:

1. Target values: Performance is judged relative to the true value for a challenge (qualitative tests), or the best available estimate of the true value (quantitative tests). In some cases the analyte and/or chemical principles available are such that it is not possible to obtain a "true" value. In these cases, performance is judged relative to the largest appropriate group of laboratories using comparable methods. For qualitative procedures (eg., organism identification and blood typing), the targets are the known, true value for the specimen, verified by referee and participant consensus. For quantitative tests, targets are participant means (for various groups), often corroborated by referee results.

2. Acceptable Ranges: Allowances for error, wherever possible, are based on clinical needs. Where such judgements have not, or cannot be made, allowances for error are based on the dispersion of the largest appropriate group of laboratories using comparable methods.

   For qualitative tests these allowances are based on expert judgement concerning the clinical impact of errors and the level of accuracy required for laboratories offering different levels of specialization. For microbiology and blood bank programs, laboratories are graded differently by "Extents", with Extent 1 being "service not provided" and Extent 4 being the highest level of specialization. Extent 2 and 3 laboratories offer less specialized identification services, and refer specimens to other laboratories when the situation warrants.

   For quantitative tests the limits are based on one of three principals, listed in decreasing level of preference:

   a. Analytical goals based on clinical needs
   b. Technically achievable limits, based on expert judgement
   c. Agreement of the "peer" or comparable group of laboratories

   Grading criteria are constantly being reviewed for elevation in the above hierarchy.

Depending on the state of the art for testing different analytes, various combinations of the above techniques are used for different analytes. These are listed in Table A. The analytes and tests listed in Table A are evaluated with procedures other than the "mean ± 2 SD" approach:

With the exception of a very few programs, the CAP does not derive overall scores for performance on Surveys. While the CAP does not compute scores, we do provide data to various state agencies so they can calculate cumulative scores using their own criteria. The CAP has also played a leading role in developing and promulgating cumulative scoring schemes that are objective and scientifically defensible (#35, 106, 168). These studies are, to our knowledge, the only published references for cumulative evaluation of laboratory performance.

CAP Grading Criteria: Rationale and Background

Establishing Target Values

The objective for CAP targets is to provide the best possible estimate of the true concentration of an analyte. For quantitative analytes, we avoid using referee laboratories to determine target values since selected groups often have their own biases. The CAP prefers using mean values obtained by participants. These are determined using a selected comparative method or the all participant mean. Where significant and meaningful method biases exist (often due to matrix effects with Survey material), the individual peer group means are the target values.

Our method is certainly as defensible as that proposed in the 1981 IG report and in use in other PT programs, where target values are established by averaging reference laboratory mean values or averaging a single laboratory's multiple analyses on consecutive days. The strength of our approach resides in our large number of individual results. The error of a mean value (standard error, or bias) will be negligible when the mean is derived from thousands of results. In addition, the large majority of participants use the most precise methods available and practice rigorous quality control techniques on a daily basis. The results from these participants continually prove to be more accurate than results from selected referees as proven against NBS definitive values. The strong prevalence of highly accurate results assures a target value with the lowest possible error.

The CAP originally used the referee method to establish targets, but discontinued doing so early in the programs' growth. The reasons for discontinuing the referee laboratory system still apply. Errors in one or two of these laboratories exert a substantial effect on reference points when the total number of such laboratories is small. Secondly, use of a small subset of referee laboratories can stagnate the target values; ie, inhibit development of new technologies which may be preferred to existing, perhaps less accurate procedures. Finally, CAP's position is that attributes of the Survey specimen (matrix effects and interference) will bias the target values. Therefore for many analytes, method differences must be allowed for and this cannot be done with a small group of referees. If a particular method has matrix interferences on Survey specimens that do not occur on patient specimens, then forcing this method to match a referee mean could introduce bias in patient specimens.

Effect of NBS Definitive Methods on CAP Target Values:

The National Bureau of Standards has developed definitive methods capable of determining true analyte values, and these are used by the CAP to verify the mean value that participants produce (#34, 36, 37, 60). This has been accomplished for several analytes: calcium, chloride, creatinine, potassium, sodium, cholesterol, glucose, urea, and uric acid. Further development is continuing to improve accuracy for many other analytes. This is the primary focus of the CAP Roger K. Gilbert follow and the CAP standards laboratory at the NBS.

No other proficiency testing program in the United States has, to our knowledge, conducted corroborative studies of their target values in this manner.

Establishing Error Criteria:

The CAP strongly supports the concept that proficiency testing or interlaboratory comparison Survey programs be guided by the medical needs for the test. The CAP has provided a leadership role in developing these criteria with two national conferences, and direct support for development of analytical goals with statistical models and interviews with practicing clinicians.

Establishing analytical goals is not easy; the article by Ross, in reference #69, gives a thorough overview of the difficulties in setting goals. Two of the more significant reasons are:

(1) All laboratory measurements have an inherent imprecision, but it is difficult to define the degree of precision that is clinically necessary. Large groups of Clinicians cannot be relied on for estimates of required analytic accuracy because in general they view the final result, which includes sources of error other than analytic error (including test ordering, specimen handling, and interpretation of results). Statistical models require making assumptions about distributions of biologic variability that may or may not be appropriate.

(2) The level of analytical error which is acceptable should depend on the purpose of the test. Laboratory testing can be divided into three areas; screening (separation of well from unwell); diagnosis of disease in particular patients; and monitoring, either for long-term trend or short-term response to treatment. Each of these levels of testing contain different analytic requirements. To mandate that a single method or method system perform at levels of expectation for all three is not technically feasible, nor even is it advisable in many cases.

In the instance of screening, there are involved two statistical distributions; a population free of "disease", and another with "disease". Both distributions include analytic variation and biologic variation. Biologic variation includes differences in results over time in a single individual and differences between individuals, all of whom may be free of disease. It is now accepted that in this mode of testing, the analytic variation is far less important than is the larger biologic variation. For example for Glucose, the biologic variation is 9.6% (#23) and analytic variation is 3.4%. In such cases, even a large reduction in analytic error is not likely to produce a significant improvement in diagnostic sensitivity or specificity as employed by the clinician.

Desired increases in diagnostic specificity and sensitivity must be related to the need for clinical diagnosis. If a clinician, for example, is not concerned with hypercalcemia until a patient's deviation from the population norm is 0.3 mmol/L, then average analytic error is already quite satisfactory. If, on the other hand, disease is over-diagnosed, then needless medical expense is incurred. The danger of over diagnosis of diseases is illustrated by hyperparathyroidism, which was over diagnosed during the past decade. Now, treatment is recommended only when there are objective clinical symptoms.

Because of these difficulties, the CAP has been cautious in introducing medical usefulness criteria into our evaluations of performance. These are done only for selected analytes where inter-method bias is minimal and, preferably, where target values have correlated with NBS definitive methods. Other fixed criteria have been implemented as standards of performance to be expected of a laboratory, irrespective of the method used. Sometimes where biologic variability is unknown or vastly different in different disease states, fixed criteria are set using the test analytic capability, but not to levels that are to clinically impractical. Other limits (particularly in chemistry), are provided by a statistical model which gives limits for accuracy based on biologic variability and loss in diagnostic efficiency (#69 and 151).

These goals are regularly reviewed and often are tightened, taking into consideration the advent of new technology and changing clinical needs for precision. As indicated in Table A, tighter criteria are under consideration for Calcium, Chloride, Cholesterol, Potassium, and Sodium. The Chemistry Committee is also considering implementing fixed limits for Thyroxine, Bilirubin, Iron, and HDL Cholesterol.

Where fixed criteria have not been determined, the error criterion used is ±2 standard deviations of the comparison group results. This procedure has been used with success for many years and is used by other PT programs. However the CAP recognizes that it is an arbitrary limit, and should be replaced whenever possible. It must be noted that the 2SD range does not automatically exclude 5% of the results. If the distributions were gaussian, 5% would be beyond 2SD, but few, if any, distributions are gaussian. Usually with CAP data more than 5% are outside of 2SD because these "unacceptable" values also include outliers (extreme values deleted from SD calculations). The CAP's concern with the 2SD system is not the percentage of excluded results, but the more important fact that different participants are graded with different allowances for error. For highly precise methods this may be much smaller than any reasonable clinical need. For other methods, the allowance could be much larger than the need. Essentially, poorer methods are given greater allowance for error, and this is not consistent with CAP purposes.

CAP Grading Criteria: Response to the 1981 Report by the Inspector General:

Much criticism of current Proficiency Test procedures has been based on a September, 1981 report by the Office of the Inspector General, titled "Proficiency Testing Program for Clinical Laboratories Operating in Interstate Commerce Administered by the Centers for Disease Control". Although the report applied to the CDC program, many of the conclusions and recommendations apply to CAP programs.

The overall thrust of the IG report was to modify CDC's and hence CAP's proficiency testing programs by using PT as an apparently single tool to evaluate laboratory performance. The IG report resurrected on-site and "blind" split samples and recommended revision of grading so that more laboratories would fall into an "unacceptable" category. The CAP viewed this report as a distortion of PT (or interlaboratory comparison) for regulatory purposes, and an overly simplistic approach to a complex problem. There were numerous factual errors in the report, and an incomplete review of then-current knowledge about goals for analytical precision.

In selecting goals for medical usefulness, the report used an overly simplistic, arbitrary selection of "acceptable" quantitative performance (in the schedule found on page 10 of the report). For example, an acceptable 20% range for bilirubin at 15 mg/dl is too broad when used for transfusional or other therapy in erythroblastosis. A 10% range for serum creatinine at a concentration of 1.0 mg/dl may not be achievable given the present state of the art.

The report further made an implied assumption that the "science of PT" has reached the point where it can effectively probe and dissect the "art of laboratory medicine". If anything, the reverse is true. Proficiency testing is limited because the test specimens vary in quality and do not resemble patient specimens. A recent national conference of government and laboratory experts reviewed new data that conclusively proved that proficiency test results cannot be used as the sole criterion for judging laboratory performance.

The CAP programs have evolved through a number of grading and scoring systems. Any and all can be subject to criticism, but to return to deviation from target values established by reference laboratories fails to acknowledge the refinements that have gone on in CAP's programs; with their support from numerous acknowledged authorities in pathology, statistics, and clinical chemistry.

Until analytical bias can be reduced to a minimum (it will always be present to some degree); until medical usefulness criteria can be successfully applied over selected medically relevant concentrations or values; until more acceptable methods exist to determine analytic truth or accuracy (ie, with definitive methods); and until PT specimens are free from matrix and inter-analytic variation and truly resemble patient specimens, peer evaluation remains a very useful tool for assessing performance.

IG Recommendations

Many of the IG's recommendations had already been implemented by the CAP at the time of the report, namely:

1. correlation with NBS definitive values for selected analytes

2. use of a comparative method (usually the defined reference method) for other analytes

3. application of fixed criteria to those analytes where bias is minimal and to which medical utility information can be added.

The CAP takes exception to the IG's recommendation that mailed PT specimens be supplemented by split-patient samples and on-site PT examination. This recommendation was based on the assumption that mailed-in PT results are superior to routine performance of a laboratory. However, the assumption that the measures of dispersion of such results substantially underestimate the dispersion of routine results has not been subjected to vigorous scientific scrutiny. One exception to this is the report by Weisbert and Barnett (Amer. J. Clin. Pathol. 38:468-472, 1986). that failed to show operator bias in the analysis of specimens. A study by Cembrowski (#13) demonstrated that proficiency test challenges frequently do receive special handling, but the author did not show that this led to improved performance.

It is difficult to disguise a PT specimen - be it mailed, hand carried, or introduced to a laboratory accessioning system in the form of a "split-specimen". The problem, however, is to devise a procedure wherein the laboratory can provide a better analysis for a single specimen. The numerous sources of analytical error include short term, long term and between laboratory variances. Any special handling on a single day will control only one of these three components. Thus duplicate analysis with subsequent averaging achieves only a minimal effect. The fact that the matrix of the specimen is very different from routine patient specimens adds substantially to the opportunity for error on a PT specimen. Results on PT specimens show "the best a laboratory can do" in a very limited sense. The best a lab can do on a PT challenge does not necessarily reflect the best the lab can do on patient specimens.

Gilbert (#23) pointed out that in order for the assumption that "laboratories do better on mailed PT samples" to be correct; three additional assumptions must obtain:

1. The laboratory must make an attempt to provide superior test results.

2. The attempt must be successful.

3. The potential for additional sources of error in the construction of the Survey program must be so small that Survey results are not actually worse than routine results.

Gilbert expressed doubt that these three assumptions are sufficiently fulfilled so as to substantially bias the statistical measures. Any "bias" that would occur would strengthen, not weaken, the reliability of the targets and, for many analytes would reduce the variability, and thereby reduce the allowance for error.

In summary, our experience is that special manipulations on PT specimens do not substantially move laboratories from "unacceptable to acceptable" for regulatory requirements.

With this in mind, on-site testing does not add to the evaluation of the laboratory; at most it will only verify how well the specimen is prepared for analysis (reconstitution, aliquoting, etc.). This observation has been confirmed by the New York State program; Dr. David Axelrod, PhD., New York State Health Commissioner, told the House Subcommittee on Regulation and

Business Opportunities that results on carried-in challenges "correlated well" with results on mailed challenges.

While on-site testing does not add substantially to performance evaluation, it may actually provide misleading information. This is because of the stability of the test materials. Considerable degradation can occur with many analytes, regardless how the specimens are stored. The limitations of stability are most severe for the formed elements of hematology, and less so for the inorganic analytes in clinical chemistry. A pre-determined target value for such specimens could be incorrect and any scoring system would be unfair.

Split-patient samples afford the attractiveness of dealing with non-lyophilized specimens. Here again however, stability and conditions of storage and collection preclude a wide-spread, national or even local program. The establishment of "truth" for concentrations or for qualitative assessments is based on the out-dated premise that a single laboratory or a select group of reference laboratories can provide such a measure of "truth". It further does not address the large variety of analytic systems and methods in the field. They, like the "truth" method or the "average of reference labs" method have their own biases. Unless the reference points can be proven to be unbiased, a scoring system based on split patient samples is too vulnerable for regulatory use.

Regarding grading criteria, the IG report stated that the CDC grading system "virtually assures acceptable results for 95 percent of the laboratories tested". This statement was accurate in 1981 since the CLIA regulations explicitly required that "the central 95% of participant results" be used in setting evaluation limits. Since the CDC program is no longer operational, the concern expressed in the IG report no longer applies. However, this same criticism has been made of CAP programs, and is not justified. The CAP has no procedure to assure passing scores for a fixed percentage of participants as in CLIA.

Table A. Analytes in CAP Surveys
that are Evaluated with Comparative Method
Means and/or Fixed Criteria

Analyte/Test	Survey	Target	Acceptable Range
Albumin	Chemistry	Peer	±0.2 g/dl or 6.7% (3)
Calcium*	Chemistry	Compare	±1.0 mg/dl (8.3% proposed)
Chloride*	Chemistry/CC	Compare	±5.0 mmol/L (4.7% proposed)
Cholesterol*	Chemistry	Compare	±15% (11.4% proposed)
Creatinine*	Chemistry/CC	Compare	±0.2 mg/dl or 9.9% (3)
Glucose*	Chemistry/CC	Compare	±6.0 mg/dl or 13.3% (3)
Osmolality	Chemistry	Compare	±2 SD
Phosphorus	Chemistry	Peer	±0.3 mg/dl or 10.7% (3)
Potassium*	Chemistry/CC	Compare	±0.5 mmol/L (7.3% proposed)
Protein, Total	Chemistry	Peer	± 5.8%
Sodium*	Chemistry/CC	Compare	± 4.0 mmol/L (3.1% proposed)
Urea*	Chemistry/CC	Compare	±2mg N/dl or 8.8% (3)
Uric Acid*	Chemistry	Compare	±16.7%
ALT	Chemistry	Peer	±25% or ±50% (depends on level)
AST	Chemistry	Peer	±25% or ±50% (depends on level)
CK	Chemistry	Peer	±25% or ±50% (depends on level)
LDH	Chemistry	Peer	±25% or ±50% (depends on level)
Other proposed limits:			
Thyroxine	Chemistry	Peer	(14.6% proposed)
Bilirubin	Chemistry	Peer	(21.5% proposed)
Iron	Chemistry	Peer	(17.9% proposed)
HDL Cholesterol	Chemistry	Peer	(23.5% proposed)
Hemoblobin	Hematology/CC	Peer	±5% or 3 SD (.)
Hematocrit	Hematology/CC	Peer	±6% or 3 SD (.)
Platelet Count	Hematology	Peer	±25% or 3 SD (.)
Red Cell Count	Hematology	Peer	±6% or 3 SD (.)
White Cell Count	Hematology	Peer	±10% or 3 SD (.)
APTT	Hematology	Peer	±10% or 2 SD (3)
Prothrombin Time	Hematology	Peer	±10% or 2 SD (3)
Factor 8	Hematology	Peer	±10% or 2 SD (3)
pH	Blood Gas/CC	Peer	±0.030
pO_2	Blood Gas/CC	Peer	5mm Hg or 7.5% (3)
pCO_2	Blood Gas/CC	Peer	3mm Hg or 7.5% (3)

Chemistry = Basic and Comprehensive Chemistry
Hematology = Basic and Comprehensive Hematology
CC = Critical Care Survey
*: Target value validated with studies by NBS definitive methods

Table B: Published References that
Discuss CAP Grading Criteria. Numbers
Refer to Bibliography List in Attachment 1

Subject/Area	References*
Analytical Goals	
Chemistry/Hematology	4,23,32,57,58,69,84,127,149,150,151,160,168
Microbiology	19,165
Statistical Models	23(Harris),57,58,69(Ross),150,151,168
NBS Definitive Values	24,34,36,37,60
Grading Criteria	
Blood Bank	16,17,120,121,122,123,173,174,175,176,177
Blood Gases	73,74
Chemistry	2,3,11,12,14,23,28,29,30,31,35,37,42,43,45,52,59,69,72,117,128,155,166
Hematology	69,97,179
Immunology	6,142,143,158,159,161
Microbiology	19,20,25,26,75,76,77,80,81,119,162,163,164
Viral Markers	131,132,134
Cumulative Performance on Proficiency Tests	35,106,168

* Underlined reference: recommended for being the most current and/or comprehensive reference.

CAP Surveys Contribution to Laboratory Improvement

Tables 1-4 of Attachment 3 and Figures 1-8 of Attachment 4 contain information documenting the current state of interlaboratory agreement on proficiency test challenges. Attachment 5 documents the number and type of laboratories participating in CAP Surveys from 1982-1987. Results are shown for different laboratory settings, for those laboratories that reported their setting to the CAP. Laboratory types are categorized according to:

Hospital--all hospitals except federal and Veterans Administration hospitals

Independent--private independent laboratories and blood banks

Physician Office--clinics, group practice laboratories with three or more physicians, and doctor office laboratories with less than three physicians

Public Health--federal and non-federal public health laboratories

Other and Unknown--federal and VA hospitals, type unknown, and other laboratories.

This data illustrates changes in interlaboratory agreement over the past 18 years. Much of this information was abstracted from the CAP publication Data ReCAP, comparing laboratory performance over the decade ending in 1980, and then supplemented with 1981-1987 CAP Surveys data. Because CAP Surveys presentations have changed over time for many analytes it is not always possible to obtain complete retrospective data.

The analytes are grouped in these presentations by similarity of the tests or similarity of the evaluation procedures. Different amounts of information were available on different analytes, so not all tables and figures are given for each analyte. The following tables appear in Attachment 3.

Table 1: This table describes the current state of agreement on proficiency testing challenges for different laboratory settings. It includes the mean, coefficient of variation (CV), range, and percentage of acceptable results for four specific laboratory types and for all results. The number of results, CV, and range are for all submitted results; the percentage acceptable is for graded results only (in some instances, not all results can be graded). Analytes or tests that appear in different Surveys generally come from different sources, so data are presented separately. Where possible, data from different Surveys have been combined.

The means for the various groups tend to be quite similar, as do the ranges. This is expected in any large group of results. Comparisons of agreement between groups are best made with the CV because this statistic is a better measure of dispersion than is the range because it is not as heavily influenced by isolated extreme results.

STATEMENT OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION BEFORE THE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT

March 24, 1988

This statement is submitted on behalf of the American Clinical Laboratory Association ("ACLA"), an organization of CLIA-licensed and Medicare certified independent clinical laboratories.[1/] ACLA thanks this Subcommittee for the opportunity it has afforded the laboratory industry to respond to the growing and alarming charges that have been leveled in the past several months. ACLA welcomes any inquiry that results in enhanced laboratory performance, and we believe that improvement is necessary in several key areas.

I. Introduction

ACLA was created in 1971 to speak for the federally regulated laboratory. Quality has been a central concern of ACLA members since the organization's inception. Indeed, this commitment to quality underlies the requirement that all ACLA members be federally regulated. The initial members of ACLA adopted this membership pre-requisite because the federal regulations applicable to Medicare independent and interstate

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[1/] This statement responds to the questions posed by the Subcommittee in its invitation to ACLA to testify at these hearings. As such, the statement discusses the quality of laboratory testing and those factors that affect it. This statement does not include ACLA's views on other non-quality issues.

laboratories were among the most comprehensive in the country, and these laboratories wished to offer membership only to those that shared their commitment to high calibre testing.

ACLA members strive to deliver accurate and reliable testing. While there is and can be no laboratory that always achieves perfect testing results, the quality of ACLA laboratories is superior, and they constantly seek to improve it. As part of this effort, ACLA members employ a variety of quality assurance techniques that go far beyond the federal requirements. For example, ACLA members utilize some or all of the following safeguards:

- Internally developed and administered blind proficiency testing programs.
- Frequent use of controls and standards.
- Standardization of testing methodologies, reagents and kits.
- Use of "gold standard" reagents and kits.
- Development of "quality circles" entailing regular meetings of persons involved in quality assurance and testing to review and improve testing and quality assurance techniques.
- Designation of quality control coordinators, supervisors and managers.
- Continuing education of technologists and other test-performing personnel.
- Ongoing quality audits.
- Ongoing quality control surveillance.
- Audits of laboratories to which tests are referred.
- Audits of manufacturers of instruments, reagents and supplies.

- Development of physician education programs addressing specimen collection techniques, interpretation of testing data and use of such data.

One ACLA member now funds five full scholarships for individuals seeking cytotechnology training and has affiliated with a university to allow cytotechnology students to rotate through the laboratory for on-site experience.

It should come as no surprise that programs such as those described above are costly. Quality is expensive! On average, ACLA members estimate that 15-30% of their expenditures is directed to quality assurance activities.

In addition to improving their own performance, ACLA members have been concerned about the calibre of testing conducted by other laboratories. Soon after ACLA was created, it began examining laboratory regulation -- at both the state and federal level. It found that, although the federal requirements were comprehensive and detailed, many laboratories were not subject to them. Independent and hospital laboratories soliciting or receiving specimens for testing from across state lines had to be licensed pursuant to the Clinical Laboratory Improvement Act of 1967 ("CLIA"). But laboratories located in physicians' offices or doing work solely for the writing of insurance, even if engaged in interstate commerce, were specifically and statutorily exempted from the provisions of CLIA.

Similarly, while hospital and independent laboratories performing tests for Medicare or Medicaid beneficiaries had to be federally certified, such laboratories, if operating intrastate and conducting no Medicare or Medicaid testing, were wholly ignored by the federal regulatory system. Moreover, physicians' office laboratories, even when testing Medicare patients, had no obligation to assure that the testing was of minimally adequate quality, reliability, precision or accuracy -- these laboratories were exempt from regulation despite their receipt of federal reimbursement.

The exemption of large numbers of laboratories from the federal programs would not have troubled ACLA members had the states adopted comprehensive regulatory programs. However, ACLA found that far too many states -- over half -- had no laboratory programs at all while others had minimal requirements with virtually no enforcement. Thus, large numbers of laboratories were escaping any regulatory attention. Little has changed since the early 1970s.

ACLA is concerned about the impact of these holes in regulatory oversight. ACLA members know, from their own experience, how beneficial quality assurance regulations can be. Shortly before ACLA's creation, the first federal laboratory quality assurance regulations were implemented: the initial Medicare Conditions for Coverage of Services of Independent Laboratories were promulgated in 1967; the CLIA regulations were adopted at the end of 1968. Accordingly, when ACLA was created in 1971, its members had just lived through the imposition of these two new federal quality assurance programs and had learned two important lessons -- (1) as a general rule, unregulated laboratories perform considerably less accurately than regulated laboratories and (2) performance improves dramatically in the first several years after a facility comes under the umbrella of a quality assurance regulatory program.

In light of this experience, ACLA members are distressed, for at least three reasons, that many laboratories are not covered by any regulatory program -- at either the federal or state level. First, although, as noted above, no laboratory is perfect, ACLA members are disturbed about inaccurate testing and they want to cure these problems and thereby improve quality. Second, the prevalence of unregulated facilities places regulated laboratories at a competitive disadvantage as unregulated facilities are not compelled to spend the added sums imposed on regulated laboratories by the regulatory requirements. Third, public confidence in the value, efficacy and benefits of laboratory testing will be undermined if attention is directed to the absence of regulatory coverage and enforcement -- a concern that the events of the last several months have proven is justified.

The Association has urged the introduction and enactment of amendments to the Clinical Laboratory Improvement Act of 1967 that would extend, under the commerce clause of the U.S. Constitution, the scope of the Act to cover all clinical laboratories -- interstate or intrastate; Medicare or non-Medicare -- regardless of the laboratory's location in a hospital, physicians' office or independent setting.

Such legislation was introduced and considered by both the United States Senate and the House of Representatives in 1976, 1977, 1978 and 1979. Indeed, the Senate passed the measure in

1977, but the House did not. Throughout these deliberations, ACLA testified before numerous congressional hearings, strongly supported the bills, and worked hard for their passage.

We regret that that legislation was not enacted for, if it had been, there would probably have been no need for these hearings today and the questions that now appear to be rocking the industry and the regulatory system would have been averted!

II. ACLA's Position

In simple and brief terms, ACLA believes that all clinical laboratories should be subject to governmentally mandated and enforced, uniform, comprehensive quality assurance regulations. Those regulations should include the following general requirements:

- (1) all laboratories should be inspected at least once annually and those inspections should be unannounced;
- (2) all laboratories should participate successfully in a federally operated, sponsored or approved external proficiency testing program that uses a nationally developed, uniform grading system;
- (3) all laboratories should utilize internal quality control practices covering the testing process, validation of that process, the recordkeeping function, corrective and preventive maintenance of equipment, instruments and facilities and proper storage and labeling of such supplies as reagents and kits;
- (4) all laboratories should employ only those personnel who demonstrate the requisite educational and experiential background.

In ACLA's view, as well as those of most laboratory experts, these requirements are the minimal criteria necessary to assure quality testing. Accordingly, any laboratory that fails to meet these requirements in a material manner, after having been provided with notice of the problem and a reasonable -- although not extended -- period of time in which to correct it, should be denied federal licensure or certification or should have such approval revoked in accordance with due process guarantees. If a laboratory represents an imminent danger to the public health, it should be closed upon the issuance of an injunction.

III. The Quality of Testing Today

By and large federally regulated, independent laboratories perform high quality testing of which they can be justly proud. Again, while no laboratory is perfect, the vast majority of testing conducted by such laboratories is accurate, precise and reliable. The advances in testing over the last 35 years have been remarkable.

While we have heard a great deal about what is wrong with some tests performed by some laboratories, we have heard very little about what is right -- and there is "lots that's right." Used properly by the clinician, laboratory testing data serves as an indispensable tool for the prompt diagnosis of disease, the selection of the best treatment modalities, the monitoring of the effectiveness of clinical decisions, and the prevention of illness. Because of their utility, laboratory tests have become an increasingly important part of the clinician's armaments in fighting disease and preserving health, and as a result physicians have grown increasingly dependent on these assays.

Federally regulated independent laboratories are aware of the importance of their service. They know that decisions may be made based on their test results and that these decisions can make the difference between life and death. They take these responsibilities seriously.

Studies suggest that quality of testing performed by unregulated laboratories, including physicians' office laboratories ("POLs"), however, is substandard. Each study that ACLA has reviewed on this subject confirms that unregulated laboratories perform considerably less accurately than regulated laboratories. For example, unregulated facilities do not always employ individuals with the type of laboratory training needed to assure quality performance. Failure to employ individuals trained in the laboratory sciences has a direct effect on the extent to which quality safeguards are utilized:

> [While 70% of the technologist supervised laboratories maintained an acceptable quality control program and records] only 26% of laboratories supervised by nurses and 42% of those supervised by "others," including staff trained on the job (OJT), were found to have acceptable programs and records. Similarly, 79% of the technologist supervised laboratories were found to exhibit acceptable practice in the maintenance of logs and records of patient reports compared with 33% for nurse-supervised laboratories and 51% for laboratories supervised by an individual without training in laboratory technology.

"Clinical Laboratory Tests and Standards," JAMA, Vol. 55, No. 3, 1/17/86, p. 397.

Significantly, laboratories supervised by nontechnologists (nurses and OJTs) were found on average to perform unacceptably on proficiency testing samples. Ibid., p. 378. "[N]on-professional laboratorians (nurses and individuals trained on the job) did not perform at the same level as trained technologists." Id, p. 381.

Because of these findings and as the literature suggests rapid improvement in testing performance after the imposition of regulations, enhanced attention should be focused on the unregulated sector. Indeed, the majority of new regulatory efforts should be directed at currently unregulated facilities so that their testing is brought up to the quality of testing performed by regulated laboratories.

In recent years, there has been a proliferation of unregulated testing -- occurring in a variety of settings, including ambulatory surgery centers, clinics, physicians' offices, emergency care centers, health maintenance organizations, and by patients at home. Because of the growth of such testing, it is especially important that these new testing sites be brought under a governmentally-mandated quality assurance program.

The largest numbers of unregulated facilities appear to be located in physicians' offices. The literature suggests that there are anywhere from 30,000 to 190,000 physicians' office laboratories. The market is growing rapidly. More than 50% of the tests reimbursed by Medicare Part B is probably performed in POLs.

The literature also suggests that the personnel performing tests in POLs tend to be less well trained and less experienced than the personnel that work in independent laboratories.[2] The failure to employ adequately trained and sufficiently experienced personnel has an adverse impact on the quality of laboratory results.[3] Unregulated laboratories do not engage in sufficient quality control,[4] and they have more random error and less precision than is found in conventional clinical laboratories.[5]

The literature concludes that there is a significant decrease in the accuracy of laboratory tests conducted in unlicensed laboratories as compared to licensed laboratories[6/] and suggests that:

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[2] Paul Fischer, M.D., "The Office Practice of Laboratory Medicine"; SPOT NEWS, June 1985, p. 4.

[3] "Clinical Laboratory Tests and Standards," JAMA, Vol 55, No. 3, January 17, 1986, p. 378-381; Baer, Daniel M., M.D., Belsey, Richard E., "Professional Consultation for Physicians' Office Laboratories," Laboratory Medicine, Vol. 1, No. 6, June 1986, p. 332.

[4] James, Karen, Ph.D., MT (ASCP), and Latham, Debi, MT (ASCP), "Establishing the Physicians' Office Laboratory," Laboratory Medicine, Vol. 1, No. 6, June 1986, p. 343.

[5] "Clinical Laboratory Tests and Standards," JAMA, Vol. 55, No. 3, January 17, 1986, p. 397; Baer, Daniel M., M.D., and Belsey, Richard E., "Professional Consultation for Physicians' Office Laboratories," Laboratory Medicine, Vol. 1, No. 6, June 1986; Walters, Carolyn Sue, MHS, MT (ASCP) and Jeter, Jan T., Ph.D., "The Use of Self Instructional Packages in Physicians' Office Laboratories," Laboratory Medicine, Vol. 1, No. 6, June 1986, p. 350; "Physicians' Office Lab Results Less Accurate Than Those of Licensed Labs, Study Shows," Medical World News, April 9, 1984, p. 47; Grayson, R.T., "Effects of Regulatory Controls on the Accuracy of Clinical Laboratory Tests," Journal of Medical Technology, 1:8, August 1984; Fischer, Paul, M.D., and Addison, Lois Anne, MLT (ASCP), "The Office Laboratory Director's Guide," JAMA, Vol. 254, No. 20, November 22-29, 1985, p. 2945.

> the legislation and enforcement of laboratory regulations improves the accuracy of clinical laboratory testing.

Ibid.

In light of these findings, ACLA was gratified by the inclusion in the Omnibus Budget Reconciliation Act of 1987 of a provision requiring high volume POLs performing Medicare testing to be regulated by January 1, 1990. We believe, however, that this provision should be broadened beyond both "high volume Medicare" and POLs and should be extended to cover all unregulated laboratories; in addition, it should be effective in 1989, not 1990.

While the most egregious quality problems appear to be associated with unregulated laboratories, where problems exist with the testing performed by regulated laboratories, these deficiencies should be addressed, as well. For example, there is no doubt that changes must be made to improve the quality of Pap smear interpretations in this country, and ACLA members are grateful for the attention that has been focused on this test as it will result in improved performance.

Although ACLA has not completed its review of this issue, it is apparent that:

[6/] Grayson, Robert Thomas, "Effects of Regulatory Controls on the Accuracy of Clinical Laboratory Tests," Journal of Medical Technology, 1:8, August 1984, p. 633.

(1) an effective, external proficiency testing program must be developed and imposed on all labs doing Pap smear analysis as soon as possible;

(2) economic incentives that encourage cytotechnologists to screen more tests than they are capable of performing accurately must be eliminated;

(3) a cytotechnologist should always screen a Pap smear in a licensed laboratory;

(4) additional monies should be directed to schools of cytotechnology to eliminate the shortage of qualified cytotechnologists;

(5) a sufficient number of negative smears should be rescreened to ensure accuracy; and

(6) physicians must collect adequate specimens.

ACLA members are constantly engaged in efforts to improve their own Pap testing procedures.

One widely discussed laboratory issue is that of false negative and false positive results. This area is complicated, involving Bayesian probability theory, but in general it relates to known shortcomings of laboratory tests. In ACLA's view, these false results stem largely from technological limitations in the testing methodologies and the laws of statistical theory, not from failures by regulated laboratories. Even in the hands of a laboratory otherwise performing flawlessly, there will be a predictable number of false positives and false negatives.

It is important as we analyze the quality of testing that we not lump all tests together and assume that what may be true with regard to one assay is necessarily true of another. The problems that may exist for one specific test, as with the Pap smear, may not apply to any other. Furthermore, an apparent "failure" of a test may result from use on inappropriate populations in the case of screening tests or from use in diagnosing diseases for which the tests may not have been primarily intended. Such a "failure" stems from the decisions of the test requester, not the laboratory which has no control over test selection or utilization. The causes of these problems are complex, and each test must be analyzed on its own merits as well as in the context of "its use."

IV. ACLA's Assessment of the Current Federal Regulatory System

In general, ACLA feels that the CLIA and Medicare independent laboratory standards are good and should be retained and extended to those laboratories that are not currently subject to them. An important federal goal should be to achieve a level playing field that subjects all laboratories to the same comprehensive, mandatory standards. As noted above, we subscribe to the theory that to be effective, a laboratory quality assurance program must build upon the four prongs of:

- personnel standards
- external proficiency testing
- quality control
- periodic inspection

The federal CLIA and Medicare independent laboratory regulations do that.

However, while the CLIA and Medicare independent laboratory standards are laudable, even the federal government has failed to achieve the level playing field that ACLA endorses. Thus, the Medicare hospital laboratory regulations are deficient insofar as they do not include comprehensive personnel standards below the director level. Personnel standards should be adopted for hospital laboratories as these facilities, more than any others, test individuals who are acutely ill and who therefore have a particularly urgent need for accurate testing. For this reason, hospital laboratories should be required by law to assure that the personnel conducting testing are well educated and highly trained.

ACLA also believes that changes should be made in the area of proficiency testing. A federal proficiency testing program is needed, and we are hopeful that one will result from this process. Once again, ACLA has not completed its review of the proficiency testing issue or of how it should be handled by the federal government; however, we are certain that the current system needs reforming and strengthening.

In addition to problems discussed above, it has been alleged that a principal failing of the current federal regulatory programs is the absence of enforcement. ACLA's experience confirms that enforcement has been relaxed in the last several years.

We have also heard that insufficient use is made of proficiency testing data for the purposes of either improving performance or initiating adverse actions against laboratories. We have no specific knowledge about such allegations, but if they are true, action is needed to correct the problems. Proficiency testing participation has an important role to play in improving and assuring quality testing, but if nothing is being done with the data, proficiency testing is of limited utility.

Additional allegations have been made that the federal laboratory programs are not sufficiently aggressive in initiating adverse actions against substandard laboratories. ACLA members have minimal experience with HCFA-initiated adverse actions. However, ACLA members are aware of a few laboratories that may be inferior which continue operating under federal approval, and we conclude from this fact that enforcement may not be as vigorous or as aggressive as it should be. We also hope that with the new intermediate sanctions authority provided by the Omnibus Budget Reconciliation Act of 1987 and heightened sensitivity to these problems, enforcement will no longer be a problem.

ACLA is aware that enforcement funds have been reduced since 1980. HCFA has conceded that in 1981 inspection funds were cut by 30%. In 1986, the Centers for Disease Control dropped their proficiency testing program due to budgetary constraints. ACLA believes that intelligent direction of additional sums of money to the HHS enforcement arms could help improve quality.

V. Components of an Effective Quality Assurance Program

As discussed above, four components must be present in an effective quality assurance program -- inspections, personnel standards, quality control and external proficiency testing. These components are interdependent and no one element is more important than another.

It has recently become fashionable to suggest that outcome measurements, such as proficiency testing, are more important regulatory tools than such input requirements as personnel standards and quality control. An examination of the Pap smear issue, however, undercuts that theory. While it may be true that the absence of a Pap proficiency testing program has contributed to Pap inaccuracy, most of the testimony on the subject places the primary identification of the problems equally on such inputs as specimen collection and cytotechnologist activity, both of which are areas that should be regulated by input controls. Moreover, the literature applicable to unregulated testing, discussed above, leaves no doubt that the calibre of the testing personnel has a direct effect on the quality of testing. Thus, ACLA urges retention of the current four pronged approach.

VI. Proficiency Testing

As noted above, a national proficiency testing grading system is needed. Laboratories should be informed in advance of the passing scores.

VII. The Role of Private Accrediting Bodies

Private accrediting bodies have played an important and beneficial role in educating laboratorians and in improving their performance. The College of American Pathologists ("CAP") has an especially fine laboratory improvement program and many ACLA members are CAP accredited because of the esteem in which such accreditation is held.

Bodies like CAP and the American Association of Bioanalysts, which offer proficiency testing, have become even more important since 1986 because of CDC's relinquishment of its proficiency testing program.

Private accrediting bodies and proficiency testing programs should continue to have a significant role. However, that role should change, as discussed in Section VIII below.

VIII. Recommendation To Improve Quality of Laboratory Testing

ACLA has three recommendations that, if adopted, would improve testing performance. First, the United States Congress should enact a law requiring the establishment of a mandatory federal laboratory quality assurance program. The new law should extend the requirements of the interstate and Medicare independent laboratory programs to all testing facilities. However, private accrediting bodies and states that adopt standards and enforcement mechanisms determined by the federal program to be equivalent to its standards and mechanisms should be eligible to enter into contracts as "deemed entities" with the federal program. Such deemed entities could offer accreditation (in the case of a voluntary accrediting body) or licensure (in the case of a state) in lieu of federally issued licensure or certification. The federal program would be required to validate on a random basis, through inspection, proficiency testing, or otherwise, the enforcment procedures and mechanisms of the deemed entity. In addition, private bodies or states that offer proficiency testing programs that are equal to the federal proficiency testing program should be allowed to continue doing so, and laboratories that participate in such federally approved proficiency testing programs should be considered to have met the federal proficiency testing requirement.

ACLA endorses state and private participation in the program for a number of reasons. First, these bodies have too much knowledge and experience to exclude them; it would be wasteful not to avail the system of that expertise. Second, the federal government cannot possibly do the job alone given the number of laboratories that would come under the jurisdiction of the new lab program; the task is simply too big. Third, making use of resources in the private sector will create demands for new accreditation services thereby resulting in more of them to assist in the enforcement of the laboratory regulations. Fourth, the adoption and enforcement of uniform, comprehensive standards will establish a standard of excellence for laboratory testing that is both attainable and desirable.

ACLA's second proposal is that laboratories be spared further Medicare cuts. Quality costs money, as discussed above. Laboratories should be paid a fair price for the services that they perform.

Since July 1, 1984, lab payments under the Medicare Program have been slashed substantially, as the following chart illustrates:

7/1/84 -- Payment levels reduced by 40% when fee schedules imposed at 60% of prevailing charges.

7/1/85 -- Fee schedules frozen instead of updated.

7/1/86 -- Payment reduced again by adoption of payment ceilings set at 115% of median of fee schedule prices.

1/1/88 -- Fee schedules frozen instead of updated.

4/1/88 -- Fee schedules for 12 tests (comprising 29 procedure codes) reduced an additional 8.3%. Payment ceilings reduced from 115% of fee schedule medians down to 100% of medians.

The GAO in its report, entitled "Medicare Laboratory Fee Schedules Produced Large Beneficiary Savings but No Program Savings" (December 1987), estimated that the first cut in 1984 reduced average per test Medicare payment to independent labs by 21%. Lowering the payment ceiling down to 110% of medians (rather than the actual reduction to 100% of medians) would have increased that per test loss for independent laboratories to 27%. Obviously, the per test reduction will be considerably greater beginning April 1, 1988, when the OBRA-87 cuts go into effect.

While ACLA understands the need to reduce the federal budget deficit, there must be a balance between economics and quality control. There are certain limits beyond which we cannot afford to go before quality will be compromised. It is significant that labs are the only provider group that has -- year after year -- been subjected to actual reductions in payment.

ACLA's third recommendation is that the United States Congress enact a direct billing law for all testing. Such laws have already been adopted by the United States Congress for Medicare and by the states of New York and Rhode Island. Under these laws, test requesters are precluded from purchasing tests from labs and then reselling them at marked up prices to the patient or his insurer. Instead, the laboratory performing the test must bill and be paid by the patient or his insurer, not the test orderer.

This payment proposal removes the test orderer from the financial aspects of the lab transaction thereby eliminating any incentives to overutilize or to select laboratories for reasons other than quality.

Test requesters should act as patient advocates. Where test requesters have a financial stake in laboratory testing, test ordering decisions may be distorted. Thus, test requesters may select a laboratory because they stand to benefit financially from such selection. They may also order more tests than are necessary or more expensive assays than are required. Test requesters should not be influenced by their own financial concerns when making testing decisions. Any arrangement that compromises the independence of a test requester in making such decisions should be prohibited. One way to begin to assure such independence is through enactment of a national direct billing statute.

Adoption of a national direct billing statute would also result in payment of fair prices to the entity that should be paid for the testing services -- the laboratory. Laboratories cannot provide high quality services if they are not paid adequate amounts.

Finally, the New York experience suggests that test requesters in direct billing states negotiate discounts on behalf of their patients, rather than themselves, increasing competition and healthy downward pressure on prices.

Thus, the benefits of this proposal are that it: (1) eliminates questionable financial incentives; (2) provides fairer prices to labs facilitating rigorous quality assurance; (3) causes test requesters to negotiate for lower prices for their patients; and (4) does not cost the ultimate payors more and in fact may cost them less.

IX. Conclusion

In its invitation to testify at this hearing, the Subcommittee provided us with a number of questions that it wished ACLA to address. We have endeavored to do so. We believe that there are now a number of questions that Congress should examine. They include:

1. Why should some Americans receive inferior testing services which can jeopardize their health and well-being simply because their physicians choose to send their testing to an unregulated or underregulated laboratory?
2. Why should laboratories located in states that have no quality assurance programs be allowed to operate without meeting standards simply because they are intrastate and do no Medicare testing?
3. Why should physicians' office laboratories escape comprehensive quality assurance regulation?
4. Why should hospital laboratories be subject to less comprehensive personnel standards than independent laboratories?
5. Has the time not come -- after 20 years -- to finally end these problems by enacting a comprehensive, quality assurance statute applicable to all laboratories?

ACLA again thanks this Subcommittee for providing this opportunity to "tell our side of the story." We look forward to working with the Subcommittee and would be pleased to provide whatever additional information we have that the Subcommittee believes would be of value.

AMERICAN ASSOCIATION OF BIOANALYSTS
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Statement of Mark S. Birenbaum, Ph.D.
Associate Administrator, American Association of Bioanalysts
St. Louis, Missouri
on the Federal Government's Role in Ensuring
the Quality of Medical Laboratory Testing
Before the Oversight of Government Management Subcommittee
Senate Committee on Government Affairs
Carl Levin, Michigan, Chairman
William S. Cohen, Maine, Ranking Minority Member
March 24, 1988

I am Dr. Mark Birenbaum, Associate Administrator of the American Association of Bioanalysts, an organization representing directors, managers, supervisors and owners of independent community clinical laboratories across the United States. Mr. Chairman, we appreciate the opportunity to share our comments with you and the Committee on the role of the federal government in ensuring the quality of clinical laboratory testing.

Laboratory Services

There are three distinct types of services in the field:

1. Clinical laboratory procedures, defined as the chemical, microbiological, hematological, serological, immunohematological (ABO grouping, Rh typing), and radiobioassay examination of material derived from the human body for the purpose of providing information for the diagnosis, treatment, or prevention of any disease or the assessment of a health condition.

2. Anatomic pathology laboratory procedures, defined as the histological and cytological examination of human cells or

Member National Commission for Health Certifying Agencies and the
National Council on Health Laboratory Services

tissues for the purpose of determining malignancy, genetic abnormalities (cytogenetics), or other pathological states.

3. Blood banking, defined as the procurement and storage of blood, or blood products, for the purpose of providing blood tranfusions.

The results of clinical laboratory procedures are provided to the patient's physician who combines this information with the patient's medical history and clinical symptoms to either make a diagnosis, prescribe treatment, or monitor a patient's health or medical treatment. The accuracy of clinical laboratory procedures is limited by the state of the art for a particular test procedure. The optimum goal of perfection, or 100% accuracy, is not technically attainable. We think it inappropriate to imply that anything less than 100% accuracy is indicative of incompetence or poor laboratory performance. In most instances, the accuracy of clinical laboratory procedures is much greater than that required by the clinician who utilizes the information (clinical relevance). We must emphasize that the function of the clinical laboratory is to provide information and data. It is not the role of the clinical laboratory to make diagnoses.

Anatomic pathology laboratory procedures by themselves are used to establish a diagnosis or the existence of a genetic defect and therefore these procedures require the services of a physician specialist (pathologist).

There needs to be a clear understanding of the distinct differences between clinical laboratory testing, anatomical pathology laboratory procedures, and blood banking.

Quality Issues

In examining the issue of quality, one must consider the following:

1. The technological (state of the art) limits on testing accuracy.
2. The source of laboratory inaccuracy.
3. The degree of accuracy necessary for clinical decision making (clinical relevance).

and 4. The role of the clinical laboratory test in establishing a clinical diagnosis.

Technological Limits on Testing Accuracy

Every laboratory procedure has an inherent level of accuracy. For many chemical procedures performed in today's clinical laboratories, this accuracy rate is extremely high. However, the premise that all inaccuracy can be eliminated is false, and the medical usefulness of any given laboratory procedure must be judged on the basis of whether the risk of an inaccurate result is outweighed by the medical usefulness of the result.

When attempting to make this judgement, a distinction must be made between the technological limits of accuracy of the method being used and what constitutes a true laboratory error. In general, techniques which require a subjective interpretation by the laboratorian are less accurate than quantitative chemical analyses or automated procedures.

Example: Automated cell counters are utilized to count white blood cells (leukocytes). A normal leukocyte count ranges from 4,000 to 11,000 and many of the automated cell counters can provide counts to within one hundred cells, which is more than sufficient to satisfy the accuracy needs of the physician.

On the other hand, a white blood cell differential is usually performed manually and requires a technologist

> to subjectively categorize certain types of white blood cells. Even under the most ideal conditions, the maximum degree of accuracy of the manual differential will never compare to automated white blood cell counts. Only a technological advance in the method for performing a white blood cell differential will allow the accuracy to become comparable to that for automated white blood cell counts.

Some laboratory procedures, due to the primitive state of the technology, exhibit a comparatively low level of accuracy but may still be medically useful. However, results that are less than 100% accurate do not necessarily mean that a laboratory error has occurred.

The Sources of Laboratory Inaccuracies

The sources of testing inaccuracies are numerous and many occur outside the laboratory. The most common sources of inaccuracies are

a) Specimen contamination or deterioration (source, collection, transport, storage, preparation)

b) Personnel errors (misreading instructions and labels; recording, reporting, and interpreting results improperly; improper technique and calculations)

c) Method error (procedural, validation)

d) Equipment error (calibration, maintenance, monitoring)

e) Reagent error (storage, concentration, purity, microbial contamination)

Laboratory analysis begins with the collection of a specimen. Sometimes laboratory-trained personnel collect the specimen, e.g., venipuncture, but many times a physician or his office staff collects the specimen, particularly for histological and cytological analyses and microbiological identification. The error rate on specimen collections by physicians is significant. According to a November 2, 1987 Wall Street Journal article about the Pap smear industry, "Leading cancer specialists say about half the Pap-test failures result because physicians take inadequate cell samples (Appendix 1)." Senator Brock Adams in his January 28, 1988, statement before the Senate Labor and Human Resources Committee's hearing on mammography screening and Pap smears stated, "...while much of the evidence will point to medical laboratory error, it is only one part of the problem. A great deal of the problem can be traced to the doctor's offices, where inadequate samples are assembled for processing." Where, we ask, are the Congressional hearings focusing on these physician errors?

The Degree of Accuracy Necessary for Clinical Decision Making

For a number of clinical laboratory procedures, the technology has become so advanced that the degree of accuracy has surpassed the level needed by the clinician. For many years AAB has pointed out that the issue of "clinical relevance" needs to be thoroughly examined. Clinical relevance is especially important since ignoring the issue may actually contribute to true laboratory problems.

Example: A test result can be reported to several decimal places, e.g., 8.23 units, but the physician is only concerned with the whole number, i.e., 8. By reporting the result as 8.23 instead of 8, chances are increased that a reporting error can occur by misplacing the decimal, e.g., 82.3 instead of 8.23. This error should be caught by the attending physician since it would probably not be consistent with the patient's medical history and symptoms, but why take the chance if the physician isn't going to use the additional information anyway?

The Role of the Laboratory Test in Clinical Diagnosis

Clinical laboratory procedures are primarily utilized for three purposes:

1. To assist the clinician in confirming a diagnosis.

2. To evaluate a patient's condition after a diagnosis has been established (monitoring).
3. Screening asymptomatic individuals.

A distinction must be made between those few anatomic pathology laboratory procedures which, by themselves, establish a diagnosis, e.g., examination of a tissue biopsy for malignancy, and the much greater number of clinical laboratory tests which, by themselves, cannot establish a diagnosis, e.g., a positive HIV-antibody test does not mean that a patient has Acquired Immunodeficiency Syndrome (AIDS). [It does mean that antibodies to the HIV virus have been produced.]

There is a great deal of misunderstanding by the general public, and even within the laboratory community, on this point. Many are lead to believe that laboratory inaccuracy will automatically result in a misdiagnosis, but that is simply not true. A competent physician knows that a key element in minimizing the effect of laboratory inaccuracy is correlating the patient's symptoms and medical history with the clinical laboratory test results. A clinical laboratory result that is not consistent with the medical history and clinical symptoms of the patient must be questioned by the physician.

The majority of clinical laboratory tests are used to monitor a patient's condition or treatment, and in this situation the diagnosis has already been established. Therefore, a random test error resulting in significant variation from a patient's usual values should be immediately apparent and the test should be repeated and confirmed before any drastic change in treatment is instituted. Again, a competent physician should understand these concepts.

One of the areas of greatest concern is a false negative (or false normal) result on a screening procedure. This is particularly critical for anatomic pathology laboratory procedures where the error can result in a missed opportunity to diagnose cancer in its early stages. The state of the art for some of these screening procedures, e.g., Pap smears, is such that a certain level of inaccurate results must be expected. In other cases the impact of a false positive is so severe, e.g., drug testing, that testing procedures are established to minimize false positives while tolerating a certain frequency of false negatives. Again, we emphasize that for anatomic pathology laboratory procedures an error can directly result in a critical misdiagnosis, whereas clinical laboratory inaccuracy does not usually result in a misdiagnosis because it is only part of the information used by the attending physician to make the diagnosis.

The Current Federal Regulatory System Governing Clinical Laboratories

There are basically two federal regulatory systems, the rules for participation in the Medicare program and the licensure statute for interstate laboratories (CLIA - Clinical Laboratory Improvement Act of 1967). Clinical laboratories have operated under these two systems for over twenty years and AAB offers the following comments and recommendations:

1. Applicability of the Regulatory Programs

The overwhelming majority of independent and hospital clinical laboratories are subject to at least one of these federal regulatory systems because the economics of the laboratory industry virtually demand that hospital and independent clinical laboratories participate in the Medicare program.

On the other hand, according to a December, 1987 GAO report, physician office laboratories (POLs), which receive approximately one-third of Medicare Part B expenditures for clinical laboratory services, are unregulated by the federal government.

2. Uniformity of Requirements

The industry is subject to different rules based upon setting, i.e., independent vs. hospital vs. physician office laboratory. The independent laboratory has the most stringent rules; hospital laboratories do NOT have personnel requirements below the level of director and may utilize private accreditation programs in lieu of federal requirements; and POLs are completely unregulated. We believe the distinction between the regulations in the different settings is reflective of the relative political power among the three major sectors of the industry rather than indicative of the need for different regulations.

All sectors of the industry, regardless of setting, should be subject to rules for internal quality control, proficiency testing, personnel, inspection, and recordkeeping.

3. Enforcement of Requirements

A great deal of time and money are expended by independent and hospital laboratories in meeting the federal requirements. All independent and hospital laboratories subject to federal regulation are inspected regularly. In addition, nearly half the states have laboratory licensure laws, some with rules that differ from the federal requirements. In that event, laboratories must also meet the state requirements, although AAB is unaware of any data establishing that the quality of laboratory testing performed in those states differs significantly from laboratories subject only to the federal rules. Again, POLs are unregulated by the federal government, and there are data showing that the accuracy of clinical laboratory testing in POLs is not as high as testing in independent clinical laboratories (Appendix 2).

Although the regulatory system is in place, there are no uniform enforcement standards. Standards and enforcement vary widely from state to state and from HHS region to HHS region. Regulations should be enforced uniformly throughout the nation with the goal of eliminating poorly performing laboratories. HCFA has been extremely lax in fulfilling its function as the overseeing agency. As a result, poorly performing laboratories continue to function.

4. Effect of the Current Regulatory System

The current federal regulatory system governing clinical laboratories has most definitely had a positive effect on the improvement of laboratory performance. Personnel requirements, quality control, proficiency testing (PT) and inspections are, generally, measurable factors that allow the evaluation of a given laboratory.

The current regulations have not been updated for a number of years and, as a result, they are not in keeping with evolving technology. This is particularly true in the area of inspections whereby redundant and meaningless records must be kept. Unnecessary recordkeeping does nothing but add overhead which in turn increases the cost per test.

Personnel Qualifications

Our summary of the sources of laboratory error (p. 4) clearly indicates that individuals who collect, process, transport, and label specimens are significant sources of inaccuracy, as are the personnel actually performing the testing procedures. Hospital pathologists have continually maintained that only the laboratory director need be qualified, and that the pathologist-director will ensure quality performance and a minimum of laboratory errors. As a matter of record, HCFA in its 1983 brief before the U.S. Court of Appeals for the District of Columbia Circuit, Case No. 83-1706 stated, "Pathologists rarely are involved in clinical laboratory tests directly. Overall, pathologists are directly involved in only approximately 1-2 percent of clinical laboratory tests (J.A. 465-466, 479, 789, 994)." Therefore, all levels of personnel play a critical role in laboratory testing, and it seems evident that properly trained and qualified personnel, at all stages of the process, are required to provide quality laboratory testing results. We cannot emphasize strongly enough that qualified laboratory personnel are an absolute necessity to minimize laboratory inaccuracies. A great deal of controversy has occurred over the issue of who is qualified to provide clinical laboratory services. Yet, as far as the federal regulatory system is concerned, over two-thirds of Medicare Part B expenditures for clinical laboratory services are paid to laboratories (hospitals and POLs) which have NO specific personnel requirements below the level of director.

When establishing personnel requirements, the rules should determine competency to perform on-the-job regardless of where or how that ability is obtained. In virtually all cases of personnel regulations in the health care field, the rulemaking process is turned into a "turf" battlefield by a college-degree caste system. This is especially true in the clinical laboratory industry: the pathologists believe only pathologists should direct clinical laboratories; Ph.D.'s believe only Ph.D's and M.D.'s should direct clinical laboratories; four-year college degreed technologists believe only they are qualified to be technologists, and so on.

This struggle results in bitter animosity between groups of laboratorians with differing educational and training backgrounds. Unnecessarily restrictive requirements lead to loss of mobility within the profession, higher turnover rates, and higher costs to the Medicare program. In addition, an insulting double standard for military veterans exists whereby most military trained technologists are not allowed the opportunity to qualify as technologists under the Medicare personnel regulations for independent laboratories (Appendix 3).

AAB believes that ALL levels of personnel providing clinical laboratory services should be required to demonstrate their competency to perform those services; the standard should apply in all settings, i.e., independent, hospital, and physician office laboratories; alternate routes to formal college training must be included; and individuals who collect and process specimens, whether they be physicians or phlebotomists, should also have to demonstrate their competency to provide those services.

AAB's Proficiency Testing Program

Exhibits A and B provide a description of AAB's Proficiency Testing Service including the scope of the program. Grading criteria are found on page 7 of Exhibit B. Statistical summaries of data on the performance of participating laboratories are found in Exhibit C.

AAB takes no action against a laboratory that fails a proficiency test, but federal and state regulatory agencies that inspect laboratories and monitor laboratory performance are supplied with copies of the proficiency test evaluations and a list of deviant laboratories. These regulatory agencies use the AAB proficiency testing data to determine a laboratory's compliance with Medicare, CLIA, and state proficiency testing requirements.

The time interval between the shipment of proficiency testing specimens to participating laboratories and the receipt by the participating laboratories of a summary of results from the proficiency testing service ("turnaround time") is critical. The shorter the turnaround time, the sooner corrective action can be instituted to correct a laboratory problem. For years AAB's Proficiency Testing Service has maintained a turnaround time of thirty days or less from the date of shipment of specimens to a participating laboratory. AAB's "turnaround time" is by far the quickest in the industry.

The AAB Proficiency Testing Service also provides participants and regulatory agencies with statistical summaries comparing results from all participating laboratories, along with a breakdown by type of instrument and/or method (see Exhibit C). Descriptive and explanatory educational material is also provided to participants about bacterial and parasitic specimens.

Need for a National Grading System for Proficiency Testing Results

A uniform grading system would be most desirable. Currently, there is wide diversity in evaluating proficiency testing data from state to state which results in a lack of uniformity in performance criteria.

As an integral part of a uniform grading system, a uniform proficiency testing program should be included because of the interrelationship of the two. The uniform proficiency testing program should include:

1. The frequency of shipping.
2. The number of challenges per discipline.
3. The complexity of each challenge.

Because of their interrelationship and interdependence, grading criteria and the proficiency testing program should be promulgated simultaneously.

The Role of Private Voluntary Accrediting Organizations In Assuring Quality In the Laboratory

Private, voluntary accrediting organizations serve an educational role through which they can have a positive impact on the quality of laboratory testing.

However, private accrediting agencies cannot substitute as regulatory enforcement agencies. As a matter of record, the College of American Pathologists (CAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the two private, voluntary accrediting agencies in the clinical laboratory field, consider their function to be educational rather than regulatory. Granting these organizations "deemed" status abrogates to the private sector the federal government's enforcement authority. AAB does not believe this is in the best interest of the patient public or the federal government and is contrary to the stated mission of these two private, voluntary accreditation organizations. In our view, the federal government is the only body that can undertake enforcement by virtue of its statutory authority. Private agencies have demonstrated that they can efficiently provide certain services, such as proficiency testing, but the enforcement of regulatory standards should remain with the government agencies. Private agencies can also provide useful input during the development of a uniform proficiency testing program and the applicable grading criteria.

The Effect of the Federal Regulatory System on the Quality of Clinical Laboratory Testing

In considering the current quality of clinical laboratory testing, one must consider two distinct populations:

1. Medicare-certified/CLIA-licensed laboratories
2. Physician office laboratories (POLs).

The quality of clinical laboratory testing in Medicare-certified/CLIA-licensed laboratories is generally good and within the realm of medical usefulness or clinical relevance. This appraisal is made on the basis of reviewing many years of proficiency testing data. In recent months, the press has made the clinical laboratory the scapegoat of bad publicity by selectively extracting bad data representing one or two anatomic pathology laboratory procedures, e.g., Pap smears, tissue biopsies, and genetic screening procedures.

Conversely, the quality of clinical laboratory testing in POLs cannot be deemed good and in many instances the accuracy is not within the realm of clinical relevance. Although thirteen states have some form of regulation governing POLs (Appendix 4), in most cases these regulations do not cover the spectrum required of Medicare laboratories - namely quality control, proficiency testing, personnel, and inspection. Thus, the factors contributing to POL inaccuracy can, in part, be attributed to a virtual lack of regulation and control. In our opinion, the state of Idaho currently has the most comprehensive regulatory system for POLs, but Idaho public health officials have stressed that voluntary systems for regulating POLs do NOT work (Appendix 5).

Other Factors Contributing to the Quality of Clinical Laboratory Services

Inescapably, reimbursement plays an important role in the quantity and quality of all health care services. AAB wishes to address two financial issues as they pertain to clinical laboratory testing.

Self-Referral of Health Care Services

The American Medical Association (AMA) has recognized the inherent conflict of interest in physicians profiting from the sale of goods or services for which they also control the demand. A good example is the current debate over the propriety of physicians dispensing prescription drugs in their own offices. In this case, the drugs sold are presumably the same drugs that can be purchased from a pharmacist, so the quality of the drugs sold has not been at issue.

Another example is the ordering and provision of clinical laboratory procedures, only in this case the quality of the service from a POL may not be as high as that provided by outside laboratories. In addition, studies consistently indicate that physicians with a financial interest in a clinical laboratory tend to order more laboratory procedures than physicians who do not have a financial interest in a clinical laboratory (Appendix 6). This means that financial incentives may cause patients to undergo unnecessary clinical laboratory procedures, and the possibility of laboratory inaccuracy affecting their course of treatment is increased.

Another problem is that the profit potential tends to cloud the physician's judgement of what he/she is willing to spend to assure quality services. Voluntary proficiency testing programs for POLs sponsored by the medical profession have been notoriously under-subscribed for years. Under-trained and untrained personnel are utilized in POLs; routine quality control procedures are not followed; and proper recordkeeping and documentation are not maintained. All of these elements of quality assurance require the expenditure of monies. Industry analysis indicates these expenses account for up to 30% of a clinical laboratory's overhead.

Further clouding the issue is the marketing and promotion of POL laboratory testing equipment and kits by at least four of the five corporations which also own the five largest independent clinical laboratory chains (Appendix 7). [The one corporation which does not market POL equipment recently spun-off a subsidiary which does market POL equipment.]

Discounting

AAB has been concerned for a number of years about the "discounting" practices of large corporate and hospital laboratories. By "discounting" we mean charging substantially less to a physician, or other client, for a laboratory procedure provided to a non-Medicare patient compared to Medicare's allowable payment for the same service.

Prior to passage of the 1984 Deficit Reduction Act, the Medicare allowable was defined as the lower of the actual charge, the customary fee, or the prevailing charge. Theoretically, discounting would lower a laboratory's customary charge (defined as the midpoint of all charges during the previous twelve months for a particular procedure). However, according to the Medicare Carrier's Manual HIM-14, Section 5114, discounts to physicians are specifically excluded from the calculation of customary charges (see letter from Yampolsky, Appendix 8). The DRA of 1984 removed the customary charge as one of Medicare's payment criteria, and shortly after its passage AAB undertook the task of inquiring whether discounting is legal. It took AAB a considerable period of time to obtain an answer from the HHS Inspector General and the Health Care Financing Administration, and our correspondence is enclosed for your information (Appendix 8).

Some of the discounts offered by large corporate and hospital laboratories to induce physician referrals are as high as 80-90% for certain procedures. However, it is still not clear whether or not these discounting practices violate the Medicare fraud and abuse statutes (see letters from Yampolsky and Kusserow, Appendix 8).

AAB believes these discounting practices are not in the best > interests of Medicare beneficiaries, the Medicare program, and the clinical laboratory industry. Discounting benefits not only the large hospital and corporate laboratories, but also their physician clients. And when physicians profit from clinical laboratory testing, they have a financial incentive to order unnecessary clinical laboratory tests which increases the likelihood of laboratory inaccuracy affecting a patient's treatment. AAB is willing to work with Congress to devise a strategy to address this important issue.

TESTIMONY OF THE AMERICAN SOCIETY OF INTERNAL MEDICINE
ON
THE FEDERAL GOVERNMENT'S ROLE ON ASSURING THE QUALITY OF
MEDICAL LABORATORY TESTING
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
MARCH 24, 1988

Testimony of William R. Smith, MD on Principles for Federal Policy on Office Laboratory Testing

My name is William R. Smith, MD. I am president of the American Society of Internal Medicine (ASIM), a federation of state societies and subspecialty organizations representing physicians who specialize in internal medicine. I practice internal medicine in Enid, Oklahoma. With me is Stephen Kroger, MD a member of ASIM's Board of Trustees who practices internal medicine in Longmont, Colorado. On behalf of the American Society of Internal Medicine, let me express our appreciation for being given the opportunity to share our thoughts on the subject of assuring quality laboratory testing.

I will start by sharing with you some basic principles that we believe are useful in discussing this subject. I will then ask Dr. Kroger to present some of ASIM's specific recommendations for assuring the quality of physician laboratory testing.

First, ASIM strongly believes that all laboratories, including physician office labs, should participate in appropriate quality assurance activities. Although we believe that there is little or no evidence to suggest that there are significant quality problems with in-office testing, we believe, nonetheless, that participation in quality assurance programs simply is in the best interests of patient care. One need not accept the view that there is a "crisis" in the quality of physician laboratory testing to support the conclusion that more can be done to demonstrate to the public the medical profession's continued commitment to assuring that physicians' own laboratories do quality work.

Second, we believe that there is an appropriate role for the federal government in promoting participation in quality assurance programs. For more than a decade, ASIM has been actively involved in encouraging physicians to voluntarily participate in proficiency testing as a means of assuring accurate laboratory data. Although we believe that the federal government should acknowledge the historical commitment of the medical profession to voluntary quality assurance programs, ASIM also believes that the country has moved beyond the point where quality assurance should be left to voluntary initiatives alone. The stakes are simply too high to expect the that public will be willing to rely solely on voluntary programs.

Third, federal regulation of physician office labs should build upon those programs that have been successfully implemented in the private sector, rather than reinventing the wheel or imposing an entirely new or inappropriate level of regulatory activity. Our own proficiency testing program--called the Medical Laboratory Evaluation program--has been in place since 1973. More recently, we have joined with the American Academy of Family Physicians and the College of American Pathologists in a more ambitious pilot program for quality assurance in physician office labs. Dr. Kroger will be sharing with you in just a few moments ways that federal regulation could build upon these effective private sector quality assurance programs.

Fourth, physician office labs provide an important service to patients that must be recognized and preserved under any federal policies to promote quality assurance. ASIM is extraordinarily concerned about a provision enacted as part of the Omnibus Budget

Reconciliation Act of 1987 (OBRA '87), which could result in the imposition of the Medicare standards for independent labs on many or most physician office labs. OBRA '87 states that any physician office laboratory that has a volume of clinical diagnostic laboratory tests exceeding 5,000 per year must meet, no later than January 1, 1990, state licensing requirements as well as "such other conditions relating to the health and safety of individuals with respect to whom such tasks are performed as the Secretary might find necessary." The House-Senate OBRA '87 conference agreement specifically states that "high volume physician office labs performing over 5,000 tests a year (including Medicare and non-Medicare) *would be treated as independent laboratories; that is the same Medicare conditions for coverage that apply to independent labs would apply in these settings.*" The conference agreement further states "the conferees intend through this requirement, to hold physician office laboratories doing a large volume of laboratory testing to the same standards that apply to independent labs." Although presumably the actual statutory language gives the Secretary discretion to do something other than to impose the standards for independent labs on physician labs, it is also likely that the Secretary could choose to comply with Congress' literal intent as stated in the House-Senate conference agreement.

Applying the standards for independent laboratories to physician office labs would have a tremendous negative impact on patient access to appropriate laboratory testing in physician offices. Although theoretically this provision was intended to target "high volume" physician office labs, the reality is that many--and quite possibly most--physician laboratories would be required to meet those standards. Any laboratory that, on average, provides 20 or more tests per day (Medicare and non-Medicare combined) would fall under the statute's criterion for identifying a "high volume" laboratory. Most physician office labs could not afford the expense that would be incurred in meeting all of the Medicare requirements for independent labs.

Consequently, if those standards are imposed on physician office labs, most physician office labs would be unable to comply, forcing them to cease operation or at least discontinue providing services to Medicare patients.

As a result, patients would be denied many of the benefits that they now obtain from in-office testing. Appended to this statement is a white paper prepared by the American Society of Internal Medicine that outlines some of the advantages to patients of in-office testing. We request that it be included in the record of this hearing.

As described in the white paper, the receipt of prompt test results and the capability to evaluate specimens directly are useful to the physician and clinically-indicated in many ambulatory patient encounters. Treatment plans can be established quickly when test results are readily available.

Modern office lab instrumentation, particularly for chemistry and hematology testing, often can provide results within 15 or 20 minutes and thereby expedite decisions about appropriate patient care. Examples of such tests include:

- Urinalysis to help detect urinary tract infection or kidney stones;
- glucose blood test at specified times for diabetic patients--particularly those with symptoms of low or high blood sugar--to enable a physician to modify quickly a patient's medication regimen;
- creatinine and BUN to monitor patients with hypertension or cardiac disease to determine whether renal function has been adversely affected by medication;
- electrolyte profile for patients taking diuretics;
- white blood count and platelet count needed immediately before administering

chemotherapy; and

- test for blood in the stool for patients with suspected gastrointestinal bleeding.

Moreover, in-office testing is convenient for patients who value being able to have their personal physician provide a full range of services in one location. Individuals with acute symptoms often can be evaluated in the office rather than being referred to a hospital emergency room, which generally results in higher costs and a delay in alleviating pain. Time-consuming trips—which are particularly difficult for the weak, the ill, and the elderly--to an outside laboratory are eliminated when physicians perform a particular test in their office lab. Many patients are anxious as they await the results of laboratory work, and having test results while the patient is in the office--or shortly thereafter--significantly reduces the amount of time patients must wait for this information.

In-office testing can also enhance the overall quality of patient care, since prompt office test results can be evaluated in light of information which has just been ascertained from the patient history and/or physical examination finding. Having just seen the patient allows the physician to correlate better all aspects of the patient examination, i.e. to compare lab test results with other findings from the patient evaluation. Explanation of laboratory findings also can be enhanced by reviewing test results with patients in person, explaining where adjustments in medication or diet might need to be made, and otherwise clarifying or reinforcing information derived from the test results.

All those advantages to patients would be lost if the Secretary of the Department of Health and Human Services (DHHS) interprets the OBRA '87 statute as requiring the imposition of the independent lab standards on physician office labs. Consequently, ASIM strongly urges Congress to consider modifying or at least clarifying the OBRA '87 provision to make clear that although some appropriate federal regulation of physician office laboratories may be needed, it is not Congress' intent that standards for independent labs be imposed upon the vast majority of physician office laboratories.

With that introduction to principles that ASIM believes should frame the discussion over quality assurance in physician office labs, I would like to ask Dr. Kroger to describe some of ASIM's existing quality assurance programs, and to suggest ways that those and other similar programs could serve as the basis for an appropriate federal policy toward quality assurance in office laboratories.

Testimony of J. Stephen Kroger, MD on Establishing a Government-Private Sector Partnership Toward Assuring Quality

Thank you Dr. Smith. I am a trustee of the American Society of Internal Medicine and an internist in private practice in Longmont, Colorado. I am also chairman of the Commission on Office Laboratory Assessment (COLA), a cooperative project of the American Academy of Family Physicians, College of American Pathologists, and ASIM to establish a physician office laboratory educational and assessment service as a means of assuring quality in-office testing. My specific comments relating to the COLA program, however, reflect only the views of ASIM, and do not necessarily represent those of the other COLA sponsors.

ASIM has a long history of supporting voluntary programs to assure quality in physician office testing. As Dr. Smith mentioned, since 1973 ASIM has sponsored the Medical Laboratory Evaluation (MLE) program, a proficiency testing service to help physicians evaluate and improve their own lab performances and take appropriate corrective action. Since 1986, data processing and other technical support have been provided by the College of American Pathologists. Designed to meet the need of physician office labs of all sizes, MLE provides physicians with:

- An external check on the accuracy of lab work;
- A cost-effective means of identifying problems with laboratory procedures and results;
- Information to help improve their laboratory testing;
- A comparison of specific instruments and testing methods.

By participating in MLE, physicians receive data comparing their own lab performance with that of other physician office laboratories performing the same procedures by identical (or similar) methods. Once enrolled in MLE, the physician receives a program manual containing instructions for participation and describing the guidelines used for evaluation. Participants are then sent kits containing testing materials in line with the specific program module that the physician has selected. Instructions for laboratory personnel are included along with the test result form, which is completed by the physician and returned to the MLE program. The results of those tests are then independently evaluated and reported back to the physician, along with the participant's summary listing results from all MLE participants by specific tests. This enables the physician to assess his or her own lab performance in both an individual and comparative sense. In addition, a newsletter designed to assist physicians with reviewing various aspects of laboratory work is sent to all participants with the evaluation reports. MLE meets current Medicare proficiency testing requirements, provided the lab is enrolled in an option commensurate with its level and scope of testing, and MLE also satisfies the laboratory proficiency testing requirements of most state health departments.

ASIM strongly believes that the MLE program and other similar proficiency testing programs have served as excellent benchmarks for physicians to evaluate the quality of their own in-office laboratories. Moreover, the available evidence suggests that laboratories that participate in proficiency testing programs do achieve a greater degree of clinical accuracy.

But ASIM's activities to promote quality assurance for all physician labs do not end with the MLE program. More recently, we have joined with the American Academy of Family Physicians and the College of American Pathologists in the development of the Commission on Office Laboratory Assessment--or COLA--program, a voluntary educational and accreditation program for physician labs. In 1986, a pilot project was conducted to allow the COLA sponsors to identify those elements necessary for an appropriate quality assurance program. Following completion of this pilot study, ASIM and the other sponsoring organizations for COLA adopted the following standards that enrolled physician office labs would be required to meet in order to achieve and maintain accreditation:

1. Physician office laboratory shall have sufficient space, equipment, facilities and supplies for the performance of their required volume of work with accuracy, precision, efficiency and safety and provide prompt and reliable reporting of results.

2. Physicians who direct the laboratory shall be responsible for ensuring that there is sufficient personnel with adequate training to conduct the work of the laboratory.

3. Each laboratory shall have a quality assurance program designed to assure the reliability and medically usefulness of the laboratory data which contains the following components:

   a. Selection of test methods appropriate to the needs of those served by the laboratory and within the technical capabilities of the facility.

   b. A quality control program which monitors precision of laboratory performance.

   c. A proficiency testing program.

   d. An instrument maintenance program.

   e. Continuing education program for the laboratory staff.

   f. Reasonable documentation of laboratory functions.

Although some of the details of the accreditation process are still being developed, it is envisioned that compliance with the COLA standards will be monitored in several ways, including independent review by COLA staff of a detailed checklist to be completed by the participating laboratory that describes and documents such elements as maintaining adequate personnel records, utilizing appropriate methods of specimen collection and handling, maintaining a procedures manual, participating in an approved proficiency testing program, complying with appropriate guidelines for safety, assuring proper maintenance of instrumentation, and so forth. Similarly, physicians would be required to document to the satisfaction of COLA reviewers that laboratory personnel have sufficient training to perform specific tests for which they are responsible. On-site inspection by COLA physician-inspectors could also be arranged at the discretion of the COLA board or upon request of the participating physician laboratory director.

Most recently, COLA conducted a survey to determine physician office laboratory interest in participating in a voluntary accreditation program such as COLA. Although the results of that study are still being processed, the preliminary findings strongly suggest that most physician office laboratories would be willing to participate in COLA.

Although COLA was intended as a voluntary program and is not yet fully operational, ASIM believes that it is appropriate for Congress and the Department of Health and Human Services to consider requiring all physician office labs to participate in an approved proficiency testing program and/or to obtain accreditation through a program such as COLA. This approach is far preferable to, on one hand, imposing unrealistic standards (such as those that are now applied to independent labs) that would threaten the continued viability of physician office labs, or, on the other hand, to simply leaving responsibility for quality assurance entirely to voluntary enrollment in private sector programs.

Requirements that all labs participate in approved proficiency testing programs and meet the standards of an approved accreditation program such as COLA would clearly meet the principles outlined by Dr. Smith at the beginning of our testimony. It would assure that all physician office labs demonstrate a strong commitment to quality assurance. It would build upon successful models and programs in the private sector, while acknowledging that the federal government has an appropriate role in assuring that physician laboratories participate in such programs. It would at the same time, however, allow patients to have continued access to quality testing in their own physicians' offices. For these reasons, ASIM strongly urges this committee to exercise leadership to promote such a government-private sector partnership to ensure quality as an alternative to requiring physician office labs to meet the same standards as independent labs.

Finally, let me briefly touch upon one other issue identified by Chairman Levin and Mr. Cohen in their letter of invitation to us: Our views on the quality of lab tests referred by our physician-member to independent or hospital labs, and on whether the federal government should do more to ensure the quality of lab test results in those settings. Although I cannot speak for the personal experiences of all internists, I believe that most of us have a reasonable degree of confidence in the test results we receive from independent laboratories. Consequently, although I don't claim to be an expert on regulation of independent labs, I personally would question the need for increased regulation of those facilities.

One thing to keep in mind is that the usefulness and accuracy of any given laboratory test depends on the clinical context in which the test is ordered and performed. The physician must ask the right questions, select the right tests to answer those questions, and accurately interpret those test results in light of other things known about the patient. When presented with an unexpected lab result, the physician may 1) ignore it, if it has little or no significance in terms of the patient's overall care; 2) repeat it to confirm the abnormality; or 3) order complementary tests that will confirm an abnormality in the patient.

If a physician receives an inordinate number of unexpected results from any laboratory, he or she will generally review these with the laboratory director and perhaps change labs if there is no assurance that things will change. If the result is from the physician's own lab, he or she will review procedures with lab personnel, review the test system for flaws and make appropriate changes. The physician may also decide to refer that test to another laboratory if he or she is unable to correct the problem.

This immediate feedback from clinician to laboratory personnel is unique to the office lab and is often overlooked in the debate over quality of laboratory testing.

Another issue often neglected in this debate is that accuracy is not the only measure of clinical utility of a laboratory test. While a test result must be sufficiently accurate for decision-making, it should also be readily available to the physician and cost-effective to his or her patient. An office lab can provide immediate results; it can also eliminate the financial burden of time, travel and return visits to the physician for interpretation of the results; and it can reduce the physical burden on the elderly and infirm by providing the service on-site. This degree of personal service to the patient and the immediate clinical feedback to the laboratory is lost to a great extent whenever an outside laboratory is used.

Dr. Smith and I would be pleased to answer any questions from the Committee.

G-BD-1137

The Case for Physician Office Laboratory Testing

A WHITE PAPER of THE AMERICAN SOCIETY OF INTERNAL MEDICINE

Surveys by the American Society of Internal Medicine (ASIM) and others indicate that more than 75 percent of primary care physicians perform some laboratory testing in their offices, while nearly all medical group practices have a lab. Although estimates on the number of physician office labs vary, it appears that, largely as a result of technological developments, such labs have become more prevalent in recent years. Many laboratory tests now can be performed quickly and accurately in the office.

A federation of 51 component societies representing more than 20,000 internists and subspecialists of internal medicine throughout the United States, ASIM is concerned primarily with socioeconomic and political aspects of medical care. The Society has a policy supporting physician office labs that perform tests for patients in a timely, efficient, accurate, and cost-effective manner. ASIM's longstanding commitment to helping physicians produce high quality lab work perhaps is best exemplified by its Medical Laboratory Evaluation proficiency testing program in which physician office labs have participated since 1973.

Advantages of Physician Office Laboratory Testing

Several benefits of physician office laboratory testing, particularly as related to providing patient care, are outlined in this section.

The receipt of prompt test results and the capability to evaluate specimens directly are useful to the physician and clinically indicated in many common ambulatory patient encounters. Treatment plans can be established quickly when test results are readily available. Modern office lab instrumentation, particularly for chemistry and hematology testing, often can provide results within 15 or 20 minutes and thereby expedite decisions about appropriate patient care. Examples of such tests include:

- urinalysis to help detect urinary tract infection or kidney stones;
- glucose blood test at specified times for diabetic patients—particularly those with symptoms of low or high blood sugar—to enable a physician to modify quickly a patient's medication regimen;
- creatinine and BUN to monitor patients with hypertension or cardiac disease to determine whether renal function has been adversely affected by medication;
- electrolyte profile for patients taking diuretics;
- white blood count and platelet count needed immediately before administering chemotherapy; and
- test for blood in the stool for patients with suspected gastrointestinal bleeding.

Physicians with office labs can review preparations such as blood smears and Gram stains directly, and they can order further diagnostic studies, if needed, while the specimen is still available in the lab.

Office testing is convenient for patients. Patients value their personal physician having the capability to provide a full range of services in one location. Individuals with acute symptoms often can be evaluated in the office rather than be referred to a hospital emergency room, which generally results in higher cost and delay in alleviating pain. Time-consuming trips to an outside lab for drawing specimens are eliminated when physicians perform a particular test in their office lab. This is especially beneficial to weak, distressed, elderly, and/or disabled patients and to those who must rely on public transportation. Travel and time costs (including leave time for employed patients), along with charges to the patient, also are lowered insofar as office testing precludes the need for return patient visits. Many patients are anxious as they await the results of laboratory work, and having test results while the patient is in the office—or shortly thereafter—significantly reduces the amount of time patients must wait for this information.

Prompt office test results can be evaluated in light of information which has just been ascertained from the patient history and/or physical examination findings. Having just seen the patient allows the physician to correlate better all aspects of the patient examination, i.e., to compare lab test results with other findings from the patient evaluation.

Explanation of laboratory findings can be enhanced by reviewing test results with patients in person. In their role as personal physician, internists are concerned that patients have a clear understanding of their medical conditions—including the results of laboratory studies. Many internists treat individuals with multiple and complex metabolic disorders. Physicians can better determine by meeting with such patients—as compared with using the telephone—whether an explanation concerning laboratory test results needs to be clarified or reinforced. This is especially helpful where adjustments in medication or diet must be made.

Office laboratory testing has the potential to enhance both the efficient use of medical office staff time and insurance claim processing. Office test results often can be incorporated into the patient record the same day the studies are ordered, and time-consuming follow-up with outside labs is not required of staff. The number of insurance claims submitted may be reduced when one entity, rather than two, bills for an office visit involving diagnostic lab studies. Currently it is necessary for an insurance carrier to process two claims for a Medicare beneficiary when clinical diagnostic laboratory tests are performed by an outside laboratory—one claim for the physicians' medical services and another for the outside lab services. Diagnosis and other information concerning the patient may not be available to an outside lab performing a test. Medicare and other health insurance representatives may make coverage determinations more easily when all relevant records are contained at one location.

Responsibilities of the Physician Office Lab Director

Lab testing arrangements must be designed to meet the needs of an individual practice, reflecting in part the nature of patient problems seen by the physician(s) and the availability and reliability of outside lab services. Even for the many practices which restrict their laboratory work within the office to very limited testing, ASIM believes that physicians who choose to perform lab studies in their office should accept several important responsibilities. They must monitor lab test quality, set standards for lab operation and staff training, and make decisions about what tests will be performed in the office lab. Office labs should have sufficient space, equipment and supplies to perform the required volume of work in an accurate, precise, efficient and safe manner. The physician(s) who direct the office labs should insure that there are enough personnel with adequate training to perform the lab tasks expected of them.

To assure the reliability and medical usefulness of the data ~~they~~ produce, office laboratories should have a quality control system containing the following components:

- test methods appropriate to the needs of the patients served by that lab;
- an internal quality control program to monitor the precision of lab test results;
- a proficiency testing program;
- an instrument maintenance program;
- complete documentation of laboratory functions; and
- continuing education for lab staff.

Physicians who have a lab in their practice should include lab-related continuing medical education opportunities among their options for ongoing professional training. And, as long as most primary physicians operate office labs, internal medicine and other primary care training programs should instruct physicians about laboratory performance demands and the need for quality control.

Conclusion

ASIM has long urged physicians to compare carefully the costs and benefits of various options in determining an optimal arrangement for their ambulatory patient lab testing. As government and health care insurance plan representatives, among others, evaluate strategies for containing health care costs, it is important for them to recognize the significant benefits to patient care, outlined in this paper, resulting from office laboratory testing, and to avoid establishing reimbursement and other policies that preclude or strongly discourage physician office laboratory testing. ■

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TESTIMONY

PRESENTED TO

THE SUBCOMMITTEE ON

OVERSIGHT OF GOVERNMENT MANAGEMENT

of the

SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS

by

THE AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY

1725 K STREET, N.W.

WASHINGTON, D.C. 20006

on

MARCH 22, 1988

The policy of the American Association for Clinical Chemistry, Inc. is that only the President, President-Elect, Past President, Secretary, Treasurer, Executive Vice President and the Association's Legal Counsel may make official statements on behalf of the Association. This limitation does not apply to the conduct of routine business transactions.

Testimony of the American Association for Clinical Chemistry

The American Association for Clinical Chemistry (AACC) thanks you for the opportunity to provide testimony to the Subcommittee on Oversight of Government Management of the Senate Committee on Government Affairs on issues of importance to the clinical laboratory.

By way of background, AACC is the national scientific society of over 9,000 professionals engaged in the delivery of clinical laboratory services. AACC is comprised of clinical chemists at the doctoral, master's and bachelor's degree level in science or medicine. The primary professional interest of the AACC membership is the application of chemistry to the diagnosis and treatment of disease and the assessment of patient health. AACC represents professional scientists working in hospitals, independent laboratories, research facilities and industries, nationwide.

As a preface to answering your questions, AACC offers six principles it believes ought to govern the regulation of clinical laboratories. To the extent that a regulatory scheme resembles these principles, AACC would support it. To the extent that the elements of these principles are not included in regulations, we would regard them as deficient.

SIX PRINCIPLES FOR REGULATING CLINICAL LABORATORIES

I. Clinical laboratories, irrespective of size or location, should be regulated by a federally approved agency. The standard for quality of laboratory performance should be the same wherever a test is performed.

The ideal agency for developing standards is a broad-based, national, voluntary organization with quality as its only vested interest.

- All physicians' office laboratories should be appropriately regulated.

II. There should be one uniform set of national standards for all clinical laboratories.

- These regulations should include personnel standards and requirements for quality assurance programs.

III. There should be a single uniform national set of personnel standards for each level of laboratory personnel.

- Certification should be required of all laboratory professionals for whom national certification programs exist.

- Continuing education should be required of all laboratory personnel.
- The standards for each level of laboratory personnel should require a flexible mix of educational requirements and relevant experience.

IV. Continuous, successful participation in a proficiency testing program, which ideally includes blind proficiency testing, should be required.

V. Both regular, announced inspections and periodic, unannounced inspections should be required.

VI. Laboratory equipment, supplies, reagents, and instruments should meet appropriate performance standards as defined in regulations.

One other influence on laboratory testing needs to be considered in any examination of laboratory quality. Quality testing does not exist outside consideration of cost. Quality assurance programs are expensive, the more comprehensive, the more expensive. These costs frequently amount to 20 to 30 percent of a laboratory's supply budget.

The currently chaotic reimbursement system is having an increasingly adverse impact on quality. Since the abrupt imposition of the laboratory fee schedule in 1984, caps have been imposed and lowered, a freeze mandated, a consumer price index increase repealed, differentials eliminated and reductions in reimbursement percentages mandated for some tests. The Government Accounting Office recently estimated that hospital and independent laboratories bore a 17 percent cut in revenue per test during the first year of laboratory fee schedule alone. The impact of the subsequent cutbacks has been even more brutal. Laboratories and laboratorians want to produce the most accurate possible test results, but they need to be compensated adequately in order to do so.

The answers to your questions follow:

1. Assessment of the current quality of lab testing, including testing performed in physicians' offices, and your views on the factors contributing to lab testing errors.

Our nation is fortunate to be able to provide its citizens with one of the best healthcare systems in the world. Laboratories governed by the kind of comprehensive regulatory system outlined in our six principles produce the best quality results. This includes hospital and independent laboratories regulated by the federal and state governments.

The farther a laboratory operates from a quality assurance system that includes personnel standards, proficiency testing and inspections, the less accurate its results are likely to be. Almost all physician's office laboratories and those un-regulated independent laboratories fall into this category.

In at least one area of testing, drugs of abuse testing, accuracy can approach 100 percent even in average clinical laboratory situations when key operating procedures are observed. An AACC study performed last year demonstrated that high accuracy in test results can be obtained by laboratories that are: involved in an external quality control program, staffed by professionally trained scientists, and conducting in-service continuing training programs for lab staff.

The 47 laboratories from across the country participating in the study achieved an overall testing accuracy exceeding 99.3 percent. Thirty-nine achieved 100 percent accuracy for all tests, the remaining eight labs did better than 95 percent. The five drugs tested were: cocaine, marijuana, opiates, amphetamines and phencyclidine (PCP). The study proves that very high accuracy levels are achievable and that high quality can be expected of drug testing.

In answer to the second part of your query, among the factors contributing to lab testing errors are: inept sample collection and handling; transcription errors, incorrect standardization or calibration; inadequacies in methodology, reagents, or equipment; and untrained or insufficiently- trained personnel.

2. Assessment of the current federal regulatory system of clinical laboratories.

The current federal regulatory system should be expanded to bring all clinical laboratories, irrespective of size or location, under its jurisdiction. In addition, the current system of regulation should be made uniform so that there is one set of national personnel standards and uniform requirements for quality assurance programs. The differing requirements of the Medicare Conditions of Participation and the Clinical Laboratories Improvement Act of 1967 should be made consistent.

3. The role of personnel qualifications, quality control standards, proficiency testing and inspection programs in assuring quality lab testing.

These are the essential elements necessary to ensure quality laboratory results.

As stated in our principles, we believe there should be a single uniform set of personnel standards for each level of laboratory personnel. Certification and continuing education should be required of all laboratory professionals, for whom certification programs exist. The standards for each level of laboratory personnel should require a flexible mix of educational requirements and relevant experience. We urge this subcommittee to resist the addition of detailed standards above these minimal requirements, such as too restrictive educational standards, or proficiency examinations of personnel, that would unnecessarily limit the flexibility needed by laboratory management and increase costs to the laboratory.

In addition, AACC strongly supports requiring uniformity between the federal personnel standards and those of the private accrediting bodies, particularly in the case of laboratory directors. The Joint Commission on Health Care Organizations and the College of American Pathologists (CAP), for example, have more restrictive standards for laboratory directors than the current federal standards. Whereas the federal government permits a non-physician clinical laboratory professional (in laboratories certified under the Clinical Laboratories Improvement Act of 1967) or a laboratory specialist with a doctoral degree (under the Conditions of Participation for Hospitals) to direct a clinical laboratory, the Joint Commission requires that the pathology and medical laboratory services be directed by a physician; the College permits doctoral level clinical scientists to direct only "in the exceptional circumstances when a physician is not available," without defining what those circumstances might be.

We believe the standards of the Joint Commission and the College are anticompetitive and unfair. They increase costs not only for the private laboratory, but also for the federal government, by precluding federally-recognized persons, non-physician laboratory directors, from delivering services. In addition, with the recent imposition of the College's newly revised standard, qualified laboratory directors could be unfairly and unreasonably forced out of currently held directorship positions. This exemplifies the danger of allowing a single organization, with vested interests, to set standards -- it may interfere with the professional practice of others. This is why AACC recommends, in its six principles, use of a broad-based, national, voluntary organization with quality as its only vested interest, to develop clinical laboratory standards.

Proficiency testing can help improve or maintain high-quality laboratory performance. Coupled with other data, it can indicate inadequacies in methodologies, reagents, equipment and performance. Proficiency testing can, and should, also provide opportunities for education and self-improvement of laboratory personnel. Proficiency testing in and of itself should not be the major criterion for quality assurance. A complete quality assurance program, including proficiency testing, is the best guarantee of quality lab performance.

AACC also supports requirements for regular inspections of clinical laboratories, including occasional unannounced inspections.

4. A description of AACC's proficiency testing program, including any action taken against a lab that fails a proficiency test and summary data on the performance of participating laboratories.

AACC runs three survey programs (called Surveys Plus) used by laboratories to augment their in-house quality control programs. Samples are mailed monthly to participating labs. Reports summarizing all results are sent to the labs. In the case of Toxicology, AACC members interpret the results in light of method biases, etc.

The three programs we offer are Therapeutic Drug Monitoring (TDM), Toxicology and Endocrinology. These programs are designed primarily to enhance quality control (i.e. samples are sent more frequently than by other survey programs) and to provide continuing education. In the case of TDM, labs have the option of requesting that we send their quarterly, graded results reports to state agencies. While this program carries approval from HCFA to meet Medicare/Medicaid proficiency testing requirements, it is not approved for labs providing interstate testing.

Surveys Plus programs allow participating laboratory directors to introduce the survey samples into the laboratory as if they were patient samples, and thereby truly test the effectiveness of their in-house quality control systems.

The AACC also cosponsors Blood Lead and Blood Alcohol surveys with the College of American Pathologists (CAP). Both of these were started at the request of the Centers for Disease Control (CDC) when the agency ended proficiency testing in these areas. AACC and CAP are also cosponsoring the Forensic Urine Drug Testing survey programs necessary to qualify for accreditation under our joint program.

5. Assessment of the need for a national grading system for proficiency testing results.

Proficiency testing programs work best with the largest possible data base; AACC, therefore, would support a national proficiency testing program. The desireability of a national grading system, however, requires further study.

6. Assessment of the role performed by private, voluntary accrediting organizations in assuring quality testing.

AACC believes that private, voluntary accrediting organizations can, and do, provide excellent oversight of laboratories. The joint AACC/CAP Forensic and Urine Drug Testing program, which accredits and inspects drug testing laboratories, is an excellent example. It is less expensive for both laboratories and the federal government than the proposed comparable federal program of the National Institute on Drug Abuse (NIDA). It is more efficient; the AACC/CAP program has completed four rounds of proficiency testing and is about to inspect and accredit drug testing laboratories, NIDA is still months behind in even publishing final guidelines. Our program promotes competition, enabling any laboratory to apply for accreditation. More competition translates into more choices and better prices for consumers, including the federal government, with the necessary assurance of quality. NIDA deliberately cut off competition by allowing only 50 laboratories to participate in the initial round of accreditation. All consumers of drug testing services will pay the price of this policy.

7. The appropriate role of the federal government in assuring quality and accountability in lab testing performed in physicians' offices.

As stated previously, the standard for quality of laboratory performance should be the same wherever a test is performed. Physician's office testing should be regulated to ensure quality results.

8. Recommendations for federal action, including views on how the federal government can best assure quality and accountability in lab testing.

The federal government should:

- provide consistent, adequate reimbursement;
- bring all laboratories under the regulatory umbrella;
- make uniform the differing requirements for laboratories participating in federal programs or being licensed by the federal government; and
- eliminate its formal recognition of and/or tacit approval of private accrediting bodies that employ anticompetitive standards.

AACC thanks you for the opportunity to provide information on the critical issues related to clinical laboratory testing. If we may provide any further information please call me, Theodore Peters, Jr., PhD, AACC's 1988 President at (607) 547-3673 or our Director of Government Affairs, Pamela Nash at (202) 857-0717.

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March 23, 1988

Hon. Carl Levin, Chairman
Subcommittee on the Government Management
Senate Committee on Governmental Affairs
Washington, D.C. 20510

RE: Oversight Hearing on the Quality of
Clinical Laboratory Testing

Dear Senator Levin:

It would be appreciated if you would cause the attached statement on behalf of American Medical Technologists to be made a part of your hearing record.

We would be glad to provide additional copies or such other information as we can in connection with this matter.

Sincerely,

Robert L. McCarty

Robert L. McCarty
Legal Counsel, AMT

RLM:eh
encl.

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March 23, 1988

STATEMENT OF AMERICAN MEDICAL TECHNOLOGISTS

Submitted To The Subcommittee on
Oversight of Government Management,
Senate Committee on Governmental Affairs
Hon. Carl Levin, Chairman

American Medical Technologists is a national certifying body and registry of some 15,000 medical technologists, medical laboratory technicians and medical assistants. AMT is just entering its 50th year of certification activity and service to these segments of the allied health personnel community.

AMT pioneered the certification of laboratory directors and supervisors. Further, AMT has structured a career ladder which provides opportunity for advancement in the profession through combining education and experience with AMT examination. Students taking medical laboratory technician training at private proprietary schools and junior colleges may take

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the AMT Medical Laboratory Technicians (MLT) examination, successful passage of which, combined with the requisite experience will earn them MLT certification. Following three years of additional experience such registrants are eligible to take the AMT examination, successful negotiation of which permits MT certification by AMT as a medical technologist. Similarly, under its Registered Medical Assistant (RMA) program instituted in 1971 AMT has certified medical assistants, who work largely in physicians offices. A portion of medical assistant training includes the performance of some basic tests. AMT has assisted in developing the type of training offered to these students to better equip them to provide limited but quality laboratory services to physicians.

AMT also sponsored and developed during the 1960s the Accrediting Bureau of Health Education Schools (ABHES), for the accreditation of private and proprietary health education institutions as well as specialized programs for MLT and MA education. The U.S. Department of Education has listed ABHES as a nationally recognized accrediting agency and the Council on Postsecondary Accreditation has also recognized ABHES to accredit medical laboratory technician and medical assistant education programs in the private sector.

AMT has also sponsored AMTIE - the American Medical Technologists Institute for Education. This foundation sponsors research for the development of studies in the medical technology and medical assistant fields.

AMT is a Category A member of the National Commission for Health Certifying Agencies (NCHCA). This organization, now a part of the National Organization for Competency Assurance (NOCA), grants membership upon showing of compliance with national standards for certification agencies such as AMT. These standards currently include periodic revalidation of certification every five years under which AMT registrants accumulate current continuing education credits or take a re-examination in order to update their credentials. It is AMT's view that membership in NCHCA and NOCA should serve to recognize certificants of such members as having the qualifications necessary to work in medical laboratories in any of the traditional laboratory settings including hospital, reference and independent laboratories, clinics and physician offices.

In 1986 the AMT Board adopted a position paper with respect to physician office laboratories, a copy of which is attached as published in AMT Events for May-June 1986. This paper concluded that all laboratories, including those in physicians offices, should operate under one set of regulations, with accommodation for the special circumstances found in physician office laboratories and with safeguards to insure that quality laboratory service is provided to all consumers.

Laboratory regulation under Federal regulations is not presently uniform. Uniformity can and should be achieved to reduce current confusion as well as to eliminate what AMT considers to be discrimination in uneven application of standards. Uniformity could be achieved by streamlining the regulations through recognition of the work that has been done by such organizations as NCHCA.

It would also help to put an end to some of the current discouraging practices which in our view have assisted in bringing about the developing shortage of medical laboratory personnel to fill existing jobs. For example in 1972 Congress, wisely in our view, authorized the giving of proficiency examinations for a number of disciplines, including medical technologists, by which a person having proper training and experience but not having a baccalaureate degree required under some of the regulations, could nevertheless qualify for those jobs. One of the provisions in the Senate Catastrophic Health Care Bill (Section 17 of S. 1127) would repeal this authority. AMT urges that this repealer not be enacted. It is not only necessary as a matter of fairness under the current regulatory scene but it is also believed essential to assist many women reentering the work force after prolonged absence, as well as veteran laboratorans trained in the Armed Forces, minorities and others who have received formal training in schools other than a college or university. Retaining the exam would also be consistent with the desire of Congress to help contain rapidly increasing health care costs.

AMT welcomes this opportunity to have this statement incorporated in the Committee's hearing record and would be pleased to assist in any further way as the Committee might request.

AMT's Position on Physician's Office Laboratories

PREFACE

Numerous factors have contributed to the current interest in physician's office laboratories. These include the recent cost containment legislation, DRG's, Medicare reimbursement, alleged unreliable results from some physicians' office laboratories, laboratory organizations representing generalist laboratory practitioners helping members find new job opportunities in a changing laboratory market and the growth of laboratory testing conducted in physician's office laboratories.

INTRODUCTION

Since its inception in 1939 AMT has championed the cause of a medical technologist directing a clinical laboratory. It pioneered the certification of laboratory directors and supervisors, and by virtue of education and/or experience and examination laboratory personnel could have a meaningful career ladder to advance in the profession. No level of technical or administrative employment should be denied the competent practitioner.

As early as 1971 AMT initiated a program for certifying medical assistants, and the first certifying examination was approved and available for the March, 1972 proctoring date. Medical assistants' principal source of employment is the physician's office. The medical assistants had, as part of their training, a component devoted to laboratory testing. While that portion of the medical assistant training was limited to performing some basic tests, AMT believed that it could be instrumental in influencing the type of training offered to these students to better equip them to provide limited but quality laboratory services to the physician.

As a result of this interest, and in cooperation with the Accrediting Bureau of Health Education Schools (ABHES) accreditation of medical assistant schools became a reality.

The Accrediting Bureau of Health Education Schools is listed as a nationally recognized accrediting agency by the U.S. Department of Education to accredit private and proprietary health education institutions and specialized programs for medical laboratory technician and medical assistant education. The Bureau is also recognized by the Council on Postsecondary Accreditation to accredit medical laboratory technician and medical assistant education programs in the private sector.

The AMT certification process which includes medical assistant certification in addition to certification for medical technologists and medical laboratory technicians earned it Category A membership on the National Commission for Health Certifying Agencies.

AMT's involvement in one segment of physician office laboratory practice, i.e., certification of medical assistants, prompted AMT President Rebecca Moretz, MT (AMT) to mobilize both the AMT Board of Directors and the Registered Medical Assistants (RMA) Executive Board to develop an AMT position statement on physician's office laboratory services. She instructed the Boards to address the following areas:

1. Type of tests to be performed and by whom
2. Quality Control
3. Proficiency Testing
4. Type of equipment to be used
5. Minimum personnel qualifications to be tied into #1
6. Consultants and their role
7. How criteria could or should be enforced and by whom
8. The use of reference labs—when?

This position paper would reinforce AMT's interest in the quality of laboratory services provided to consumers as evidenced by AMT's program of certification of personnel.

AFFIRMATION

1. Regardless of the size of the laboratory setting the patient deserves the highest quality of laboratory service available.
2. Certified personnel should be employed by physicians in office laboratories.
3. Quality Control should be mandatory and supported by an appropriate proficiency testing program.
4. Regardless of the setting all laboratories should be measured against one set of regulations.
5. The kind and amount of testing done in a physician's office laboratory should determine the type of certified personnel necessary to do the job.
6. Those responsible for the management of the physician's office laboratory should recognize and acknowledge testing limitations and use the resources of references laboratories when necessary.
7. Medical Technologists should be utilized as consultants to physician's office laboratories when the scope of testing performed and equipment utilized go beyond the capability of the individuals employed in the facility.
8. The laboratory should be directed/supervised by a physician, a recognized Medicare laboratory director, or a certified medical technologist.

THE ISSUES

A. *Type of Tests to Be Performed and by Whom*

There should not be any limitations on the type of tests performed in the physician office laboratory provided the personnel, equipment and standards for quality testing are available.

1. A certified medical assistant should be capable of providing accurate results when basic tests required by the physician are performed. The services of a consulting certified medical technologist should be utilized on a regular basis. If a full range of testing is provided the services of a certified medical technologist should be mandatory.

2. A certified medical laboratory technician should be capable of handling a variety of testing procedures requiring a limited exercise of independent judgment and discretion. The services of a consulting certified medical technologist should be utilized on a regular basis. If a full range of testing is provided the services of a certified medical technologist should be mandatory.

B. *Quality Control/Proficiency Testing*

Every physician's office laboratory regardless of size should maintain a quality control program (daily on tests

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Continued: AMT's Position on Physician's Office Laboratories

performed). The facility should also subscribe to a Proficiency Testing Program to cover all tests performed in the physician's laboratory.

C. *Minimum Personnel Qualifications*

Personnel certified by organizations that are Category A Members of the National Commission for Health Certifying Agencies should be utilized in addition to those medical technologists who have successfully passed the Proficiency Examination administered by the U.S. Department of Health and Human Services. Other certifiers of medical laboratory personnel should show evidence that the certifying body meets the criteria of NCHCA.

D. *Suggestions on How Criteria Could or Should Be Enforced and by Whom*

AMT supports the concept that all laboratories, regardless of size and location—including those operated by local, State and Federal governments, should conform to a single set of standards, such as the Medicare Standards for Independent Laboratories.

It is AMT's suggestion that each state conduct a statewide registration of physician's office laboratories and charge an appropriate fee to cover the cost of this annual registration. Such fees should be utilized to support a five year study of these facilities to determine the quality of service provided. The study would monitor the following:

1. Size of setting/personnel/equipment/tests involved.
2. Quality Control and Proficiency Testing data as submitted to the Division/Bureau of Laboratories for analysis. Evidence of substandard performance would result in an on-site consultative visit, at the offending laboratory's expense.
3. Testing charges and costs.

Each state could analyze its data and compare it with the data/analyses from other states. A coordinating body, such as the Council of State Governments, could study the data and issue a report and recommendations regarding physician's office laboratory practice. One set of regulations should be adopted as the standard of practice for *all* laboratories. The applicability of each provision would depend upon the particular circumstances of practice in each physician's office laboratory. The application of the regulations should assure quality laboratory service to the consumer. AMT believes that any hasty decisions to apply current Medicare or hospital regulations to physician's office laboratory practice may jeopardize the ongoing services physicians now offer their patients.

E. *In-House Testing or Using Reference Labs*

If the scope of the service that the physician's office laboratory provides has been established by the physician(s), and this is in keeping with the type of staff, equipment and space available, additional tests falling outside these parameters should be referred to a reference laboratory.

It is incumbent on the physician to carefully screen/investigate the reference laboratory that will be utilized for this purpose.

In addition, the physician(s) and the laboratory personnel should be instructed by the reference lab as to:

1. How the specimen is to be collected
2. How the specimen is to be shipped/transported
3. Any other special instructions that may be applicable to the specific testing to be performed.

Such services should be appropriately compensated, an arrangement which would encourage physicians to utilize reference laboratories for many of the tests they require and still remain economically responsible to the patient. While some abuse has been noted in physician mark-up of fees, current drawing fees simply force physicians to perform tests in-house rather than using reference labs.

CONCLUSION

AMT reaffirms that *all* laboratories should operate under one set of regulations with accommodations for the special circumstances found in physician's office laboratories. In all cases, safeguards must insure that quality laboratory service is provided to the consumer.

Approved by the American Medical Technologists
Board of Directors, April, 1986

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STATEMENT

By

Health Industry Manufacturers Association

Before the

Subcommittee on Oversight of Government Management

Committee on Governmental Affairs

United States Senate

March 22, 1988

an association representing the medical device and diagnostic product industry

The Health Industry Manufacturers Association (HIMA) wishes to thank the Senate Subcommittee on Oversight of Government Management for the opportunity to comment on laboratory testing. HIMA's members manufacture about 90 percent of the medical devices, diagnostics, and health care information systems made in the United States. Among these products are in vitro diagnostic test systems used in hospital laboratories, commercial laboratories, and physician office laboratories.

Manufacturers are committed to quality in laboratory testing and share the committee's concerns about reports of errors in laboratory testing. We believe that all parties--labs, physicians, payers, manufacturers, and others--have a responsibility to assure the quality of test results.

Recognizing this, however, we must not overlook the fact that in vitro diagnostic testing--testing performed on body fluids or tissues removed from the body--has improved significantly over the past 30 years. This improvement is due, in large measure, to the manufacturing and marketing of test systems that have reduced variability and human error in testing. While in vitro diagnostic testing is not perfect, it is extremely accurate and an increasingly important factor in improving the quality of health care. One of the reasons for this is that more and better medical tests are available. Over the past 30 years, manufacturers have increased the number of substances that can be measured, increased the accuracy and precision of the tests, and, by simplifying the test procedures, broadened the settings in which the tests can be used appropriately. These improvements in laboratory testing enable doctors to save lives, prevent suffering, and lower health care costs. Here are a few examples:

- Newborns are routinely tested for phenylketonuria, or PKU, which, untreated, can lead to mental retardation. If PKU is detected through this screening test, mental retardation can be prevented through diet and medication.
- Glucose monitoring helps diabetics to lead more normal lives.
- Strep tests have saved countless children from the life-long effects of rheumatic fever.
- Occult blood tests facilitate early diagnosis of colon cancer--while the disease can be successfully treated.
- Victims of tick-borne Lyme disease were once diagnosed as arthritic and thus denied effective treatment. A simple diagnostic test can now detect Lyme disease in a patient's blood in less than two hours, and the disease can be successfully treated with antibiotics.
- Cardiac enzyme tests can help in the successful management of heart attacks and warn doctors to take preventive measures.

Manufacturers are proud of the quality and diversity of in vitro diagnostic tests now available. They are also aware of the limitations of the testing and spend a good deal of effort and money to improve them.

The subcommittee has asked us to comment on the factors contributing to lab testing errors. A recent conference on "Managing the Quality of Laboratory Test Results"[1] identified more than a hundred factors that can affect the quality of test results--from improper posture on the part of the patient at the time of sample collection to misinterpretation of the results on the part of the doctor.

The latter point needs to be underscored. While diagnostic tests are important tools, they don't make diagnoses. Doctors make diagnoses.

In the words of Dr. Paul Fischer, a professor of family medicine at the Medical College of Georgia, testifying on medical testing before the House Small Business Subcommittee on Regulation and Business Opportunities, March 2, 1988, "a test is only as good as the clinician who has ordered it."

In other words, a doctor must know, through education and experience and knowledge of the patient, what tests to order and how to interpret the results.

While we believe that quality results can be, and are being, achieved in laboratory testing--whether it is performed in hospital labs, commercial labs, or physician office labs--we must caution the committee that 100 percent accuracy is a goal that will never be reached. Even if we could control all the human factors in testing, we probably could not make perfect tests. The complexity and the variability of the human body make that impossible. The relevant question is whether the tests yield medically useful information.

Although in vitro diagnostic tests will never be perfect, they can be made better and they are being made better. For example, when cholesterol testing began in the 1940's, the variability of results was almost 24 percent. Today, that figure is 5.7 percent, according to the most recent figures from the College of American Pathologists, and we expect it will be less than 5 percent in the near future. This improvement is due to better chemistry procedures, improved electronics and testing technology, and to the availability of a standardized reference material, as well as to better quality control procedures in laboratories.

The manufacture of in vitro diagnostic tests is regulated by the Food and Drug Administration, which is charged with ensuring the safety and efficacy of all medical devices and diagnostics. An

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1. Proceedings of the 1986 Institute on Critical Issues in Health Laboratory Practice: Managing the Quality of Laboratory Test Results in a Changing Health Care Environment, edited by Stanley L. Inhorn and Betty V. Addison, sponsored by the Centers for Disease Control and the University of Minnesota, The Du Pont Company, 1987.

important component of FDA regulation is the IVD labeling requirement. Products must be labeled so that the customer knows the following information:

- Accuracy of the test
- Precision of the test
- Sensitivity of the test
- Limitations of the test, i.e., what substances, such as medicines, in the specimen might interfere with accurate test results
- Scientific principles of the test procedure
- How to calibrate the test
- How to conduct quality control procedures
- Scientific references that document the above information.

In addition, manufacturers compete on the basis of the quality of their products and services. They are constantly improving and refining their tests and many offer a variety of services with their products, including training programs, service contracts and quality control programs. Many staff telephone "hot lines" to help solve any problems and provide on-site technical support to make sure the equipment is working. Improvements in all of these services will always be possible, just as tests themselves will be better tomorrow than they are today. This perpetual improvement constitutes the greatest value to society and the greatest challenge to testing proficiency.

Before moving to comment on federal requirements of clinical laboratories, we would like to mention a topic not formally on the Subcommittee's agenda. The relationship between reimbursement reductions and laboratory quality is an area that needs to be explored. Medicare payments for clinical laboratory tests have been reduced more drastically than any other segment of the Medicare program. Additionally, creation of the prospective payment system has increased pressure on hospitals to cut back on laboratory operations. If reimbursement is cut too much, quality may suffer. We are pleased that Congress has recognized this potential problem and has called for a study of this issue by the General Accounting Office. We suggest that Congress impose a moratorium on reductions in laboratory reimbursement until the results of this study are known. Congress should also remember that laboratories may have to bear the added costs of compliance with new regulations. Continued Medicare payment reductions may be inconsistent with the higher expectations that regulations impose.

The Subcommittee has asked for our assessment of current federal regulation of clinical laboratories. Although we are quite familiar with FDA regulation, HIMA has no special knowledge of the current federal regulatory system for the laboratories themselves that will aid the subcommittee in its work. We do, however, have some thoughts on how the federal government can help assure quality and accountability in medical testing. The government should:

- Encourage participation in proficiency testing programs.

  HIMA believes that the voluntary proficiency testing programs offered by such groups as the College of American Pathologists (CAP), the American Association of Bioanalysts, and the American Society of Internal Medicine have been of substantial assistance in helping laboratories improve their testing performance. And, as the subcommittee knows, the CAP, in conjunction with the American Society of Internal Medicine, will initiate by the end of this year a proficiency program for physician office laboratories. One of the criticisms of such voluntary programs is that only the best laboratories choose to participate in them. If Congress believes that additional regulation of medical laboratories is necessary, mandatory participation in a recognized proficiency testing program, where available, would be an effective additional way to assure quality in laboratory testing. It would also be cost-effective, since the machinery is already in place and a new and costly layer of government bureaucracy would not be required.

- Encourage the diffusion of new testing technology.

  HIMA believes that medical laboratories--whether they are located in hospitals, in physicians offices, or in freestanding facilities--can and must achieve quality results. While the basic quality principles are the same regardless of the test setting, the actual practices used to achieve these principles may vary depending upon the instrumentation. Any additional regulation of laboratories should be devised with that end in mind. Since advances in technology improve the accuracy of test results, laboratory regulation should allow and encourage the adoption of appropriate new testing technologies. Technology continues to make formerly complex lab procedures very routine. It is important that regulation not impede the application of new technology and its diffusion to a variety of clinically appropriate settings, including doctors' offices and patients' homes.

- Study what kind of regulation, if any, would contribute to improved quality in laboratory testing.

  Although there has been a barrage of negative media reports on laboratory testing, little hard scientific data has been cited as support. We are aware of several pending studies on the quality of laboratory testing, by the General Accounting Office, the Health Care Financing Administration (HCFA), and the Inspector General of the Department of Health and Human Services. We believe Congress should use the results of those studies to determine what specific regulatory response will materially improve quality. Various state regulatory models may also be helpful.

- Revise the 1987 OBRA requirements for physician office labs.

  Test systems for doctors' offices are designed to be safe and to achieve quality results even when used by persons with minimal training. Quality controls are built into the system. Testing in doctors' offices offers substantial benefits to patients by speeding diagnosis and treatment. These benefits would be jeopardized by a regulatory scheme that did not take into account the technological advances that have made testing in this setting possible. HIMA believes the OBRA 1987 requirement that HCFA regulate physician office laboratories with more than 5,000 tests per year should be abolished--in the absence of any evidence that regulation based on any arbitrary number would contribute to improvements in quality. The practical effect of this requirement would be to strain HCFA resources by requiring regulation of virtually every physician's office in the country. HIMA believes that a better approach would be to base the requirement for regulation on the skill required to perform the tests. The current requirement is analagous to requiring people who drive cars and people who drive jet planes to have the same kind of license, if they travel 5,000 miles a year.

- Provide adequate funding for FDA so that new diagnostic tests are properly reviewed in a timely manner.

  FDA plays a key role in assessing the efficacy of *in vitro* diagnostic tests. FDA should have sufficient resources to perform this important function. HIMA has appeared before the Senate and House Appropriations Subcommittees supporting more FDA resources. We would welcome this Subcommittee's help in this area.

- Provide adequate funding for the National Bureau of Standards for basic measurement science, including the development of new reference methods and materials.

- Provide adequate funding for biomedical research, the source of many new tests.

- Temper the justifiable concern over health care costs with a recognition that Medicare payment reductions can ultimately detract from quality.

  We believe the pending studies in this area should clarify the relationship between costs and quality and think it appropriate for Congress to consider a moratorium on additional Medicare reductions until there is a better understanding of the impact of such reductions.

HIMA is prepared to work with the Congress to develop a system that ensures patient access to high quality clinical laboratory services throughout the nation. HIMA staff is available to the Subcommittee to pursue that goal.

FREQUENTLY ASKED QUESTIONS ABOUT MEDICAL TESTING

Health Industry Manufacturers Association (HIMA)
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March 2, 1988

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FREQUENTLY ASKED QUESTIONS ABOUT MEDICAL TESTING

I. DEFINING THE TERMS

1. WHAT IS MEDICAL TESTING?

The term "medical testing" refers to a range of methods that can be used to help make a diagnosis or monitor a condition or treatment. Examples are home pregnancy kits, mammography for early detection of breast cancer, and tests that help physicians monitor the level of chemotherapy agents needed for leukemia patients.

2. WHAT DOES THE TERM "IN VITRO DIAGNOSTICS" MEAN?

In vitro diagnostics, or IVD's, are tests performed on a body fluid or tissue removed from the body. They are sometimes called "lab tests." The results of these tests are one factor in making a diagnosis.

3. WHAT OTHER KINDS OF TESTS ARE THERE?

A variety of important tests are performed which do not fall into the category of lab tests. These include, among others, blood pressure monitoring, physical stress tests, glaucoma tests, and diagnostic imaging.

4. WHAT IS A SCREENING TEST?

A screening test is an analytical determination, examination or other procedure that can be applied rapidly for the identification of an unrecognized disease or condition. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be definitively diagnostic (although it may be) and persons with positive or suggestive findings ordinarily undergo further confirmatory testing and necessary treatment. A usual requirement for a screening test is that it be quick and relatively inexpensive.

5. **WHAT IS A CONFIRMATORY TEST?**

A confirmatory test is a follow-up test performed on people who tested positive in a screening test. Confirmatory tests are often more technically demanding and time consuming than screening tests. Therefore, it is more cost effective to use the screening tests initially.

6. **I'M CONFUSED ABOUT THE TERMS "ACCURATE, "PRECISE," "SENSITIVE," AND "SPECIFIC." DO THEY ALL MEAN THE SAME THING?**

You're right to be confused. All these words sound interchangeable, but to testing experts, each means something quite definite:

- Accuracy means how well the results of the test match the actual concentration of the measured substance in the people tested.
- Precision means the ability of a test to produce the same results when repeated on the same sample.
- Specificity refers to a test's ability to show a negative result in individuals who do not have the substance being tested for in their body fluids.
- Sensitivity refers to a test's ability to show a positive result in individuals who do have the substance being tested for in their body fluids.

7. **WHAT IS A FALSE POSITIVE?**

A false positive is a test result that wrongly indicates the presence of a certain level of a substance in body fluids.

8. **WHAT IS A FALSE NEGATIVE?**

A false negative is a test result that wrongly indicates the absence of a substance in a person's body fluids.

9. WHAT IS "PREVALENCE?"

Prevalence is the number of individuals who actually have the disease or condition in a given population. For example, the prevalence of, say, tuberculosis might be 1%: 1,000 cases out of a population of 100,000.

Prevalence is often incorrectly used interchangeably with "incidence." Incidence is the rate at which new infections or disease are introduced into a population. Incidence is expressed in terms of number of cases over a given period of time, usually one year.

10. WHAT IS "PREDICTIVE VALUE?"

Perhaps to oversimplify a bit, predictive value indicates how well a test performs when used on a given patient population in a "real-world" setting. It is based on a test's sensitivity and specificity, combined with the prevalence of disease in the population being tested.

The predictive value of a positive result is the percentage of positive results that are true positives. The predictive value of a negative result is the percentage of negative results that are true negatives. Predictive values are the best measures of the likelihood of obtaining false test results when testing individuals in a given population.

II. USING THE TERMS

11. WHY ARE THE TERMS "PREVALENCE" AND "PREDICTIVE VALUE" IMPORTANT?

Even if a test scores very high in sensitivity (the ability to correctly spot patients who are actually ill) and very high in specificity (the ability to show negative results in patients who are actually healthy), the prevalence of a disease will strongly influence the test's predictive value, and, thus, the accuracy and the medical interpretation of the test.

In general, the lower the prevalence of disease (i.e. the fewer people who have it), the more sensitive and specific a test must be to yield results that are as reliable as a test for a disease with high prevalence.

In their often cited book on measurement issues, Beyond Normality [John Wiley and Sons, Inc., 1975], Robert Galen and S. Raymond Gambino point out that the prevalence of the disease is far more important than common sense would suggest. To illustrate, the authors state that if an extremely reliable test had absolutely no false negative results at all, and there was only one false positive per 10,000 subjects who were free of the disease -- but the disease had a very low prevalence of between 5 and 10 per 100,000 -- then the predictive value of an abnormal result would be only 50 percent. That is, half of the positive results would be false positives.

Of course, tests of relatively low predictive value may be medically useful and, in combination with other factors, contribute to an accurate diagnosis. But, most importantly, this example points out the real impact of prevalence: regardless of a test's sensitivity or specificity, prevalence of a disease in a population can have an enormous impact on the predictive value of the test.

12. HOW DOES THIS RELATE TO THE CURRENT CONTROVERSY OVER TESTING?

It shows that testing for a disease at low prevalence can make even an incredibly sensitive and specific test -- or combination of tests -- look less reliable. This lack of understanding can cause alarm and confusion.

Specifically with regard to the HIV antibody test, this situation has occurred. When the test is used in low risk populations -- that is, where prevalence is very low, such as in volunteer blood donors -- the frequency of false-positives is much larger than when used in high prevalence populations, such as drug users or homosexuals. For this reason, it is especially important that confirmatory tests be used, -- together with appropriate medical investigation and follow up testing -- before the diagnosis of HIV infection is made in an individual from a low-risk setting.

13. HOW ACCURATE DOES A TEST HAVE TO BE TO BE USEFUL?

A test must be accurate enough to provide clinically relevant information that, taken together with the physician's findings on examination, the patient's medical history, and the results of other tests, will help a physician make a correct decision.

III. CONSUMER TIPS

14. HOW CAN PATIENTS MAKE SURE THE TEST THEY'RE GETTING IS NECESSARY, APPROPRIATE AND SAFE?

Patients should ask their doctors about the test. What's the test for? What can be learned from the result? What would be changed if the test were omitted? Is there any risk? If so, how does it compare with the risk of not taking the test? Is there an alternative to the test? Is a backup or confirmatory test needed? In addition, patients should ask about the accuracy rate of the test -- information that is clearly shown on the manufacturer's label. In short, patients should involve themselves in the testing process, by informing themselves and asking questions.

15. HOW CAN A PATIENT BE SURE HIS MEDICAL TEST IS SENT TO A RELIABLE LAB?

Patients generally can't choose their own labs, but they can ask their doctor about the qualifications of the lab. Doctors owe it to their patients to choose a reliable lab.

IV. REGULATION

16. HOW ARE MEDICAL TESTS REGULATED?

In Vitro diagnostic tests are regulated by the Food and Drug Administration. All manufacturers who want to market a medical test or other device must first obtain FDA's clearance. To do this, the manufacturer must comply with all FDA requirements on labeling, registering and listing a product. The agency reviews the labeling and all advertising for medical tests to assure that the instructions are clear and reflect what the test really does.

FDA also reviews a firm's quality assurance and manufacturing practices and possesses a variety of enforcement tools to assure that faulty products do not reach the market.

17. HOW ARE MEDICAL TESTING LABORATORIES REGULATED?

Hospital labs are regulated by Medicare, if they receive Medicare reimbursement. Some hospital labs are regulated by the Clinical Laboratories Improvement Act of 1967 (CLIA) which sets personnel standards and quality control requirements for labs.

Independent labs, which are not connected to a hospital or doctor's office, are regulated mainly by CLIA if they engage in interstate commerce or perform Medicare work. In addition, 33 states regulate independent labs.

Physician office labs have generally been exempt from most state and federal regulation provided they performed tests exclusively for the patients of the physicians in whose offices they were located. However, in December 1987, Congress passed legislation that requires physician office labs processing more than 5,000 tests annually to meet the standards of independent labs. This law goes into effect in 1990. With regard to state regulation, several states regulate group practice labs. Four states require physician labs to participate in proficiency testing. Three states require comprehensive regulation of most physician office labs. Several other states regulate physician labs to varying degrees.

Voluntary standards developed by independent accreditation groups such as the College of American Pathologist, also impose a variety of quality assurance and training standards.

V. TESTING LOCATION

18. WHERE ARE LAB TESTS PERFORMED?

According to industry sources (Biomedical Business International), the majority of tests (approximately 60 percent of the total) are performed in hospital laboratories. Approximately 30 percent of all tests are performed in independent clinical laboratories. The remainder are performed in clinics, health maintenance organizations, physicians offices and in the home.

19. **WHY DO WE NEED LABS IN PHYSICIANS' OFFICES?**

Tests performed in doctors' offices can save time and money and lead to earlier treatment.

VI. AIDS TESTING

20. **HOW ARE PEOPLE TESTED FOR AIDS?**

There are no tests for AIDS per se, but there are tests for the presence of antibodies to the Human Immuno-Deficiency Virus (HIV). The ELISA (Enzyme-Linked Immunosorbent Assay) is used for screening. People who test positive are asked to take a confirmatory test known as the Western blot test. Test results should not be reported until and unless a positive ELISA is confirmed by Western blot.

21. **HOW ACCURATE ARE THESE AIDS TESTS?**

When this two-test system is used, the chances of a false positive result in a low-prevalence population is less than 1 in 100,000, according to the Centers for Disease Control.

22. **WE'RE TALKING ABOUT HUMAN BEINGS, NOT NUMBERS. ISN'T EVEN ONE FALSE POSITIVE TOO MANY IF IT RUINS SOMEBODY'S LIFE, MAYBE DRIVES SOMEONE TO SUICIDE?**

AIDS testing must go hand-in-hand with counseling. Individuals who test positive should be made aware of the limitations of such testing. If there is no evidence to support the diagnosis of HIV infection from the history and symptoms of the patients, additional tests may be run as a check.

There will never be a perfect test, but researchers and manufacturers are working on better AIDS tests, including tests that will detect the virus itself rather than the antibodies.

It should be noted that the AIDS virus itself was only identified in 1984. The laboratory community has responded to the need for an accurate test remarkably quickly.

VII. SPECIFIC TESTS: CHOLESTEROL AND DRUGS

23. EVERYBODY AGREES IT'S IMPORTANT TO CUT CHOLESTEROL, BUT CAN YOU REALLY RELY ON THE RESULTS OF CHOLESTEROL TESTS?

According to the College of American Pathologists Proficiency Survey for the last quarter of 1987, laboratory cholesterol tests are 94.3 percent accurate. A committee of the National Institutes of Health, in cooperation with manufacturers and the clinical laboratory community, has launched a campaign to improve methodologies and standardize measurement through calibration of instruments according to a national reference material.

24. HOW ACCURATE ARE DRUGS OF ABUSE TESTS?

According to a study conducted by the American Association for Clinical Chemistry in April 1987, tests for drugs of abuse in urine samples can exceed 99 percent accuracy when proper testing procedures are followed. Forty-seven laboratories from across the country participated, and thirty nine identified drugs of abuse in samples with 100 percent accuracy. The remaining labs scored better than 95 percent. According to the AACC, this test showed that "testing accuracy is an achievable goal...if the lab is staffed with certified professionals using appropriate quality assurance procedures." AACC has published guidelines for selecting and monitoring drug testing laboratories.

VIII. CRITICISMS OF TESTS

25. ARE SOME MEDICAL TESTS DOWNRIGHT DANGEROUS?

It depends on what you mean by downright dangerous. No test is absolutely, positively free from risk. Even drawing a routine blood sample involves a small degree of risk. In vitro tests are performed on specimens drawn from the body. Once the specimens are taken there is obviously no risk. Other tests may involve some risk. It is for the doctor and the patient to decide whether or not the potential benefit of the test outweighs the risk.

The medical device industry, working with the Food and Drug Administration, strives constantly to minimize the risks by devising new and better tests. It's also important to remember that many of these diagnostic procedures under scrutiny are used on people suffering from acute disease or severe trauma--people who are seriously ill.

26. **AREN'T A LOT OF TESTS UNNECESSARY -- JUST A WAY FOR DOCTORS TO MAKE MONEY OR AVOID LAWSUITS?**

Undoubtedly, some doctors practice "defensive testing" to avoid possible malpractice suits. One possible cure for this ill may be reform of the tort laws. Public and private insurance plans, through their reimbursement practices, are encouraging doctors and patients to be more judicious in their use of medical tests. Media attention is also creating more savvy patients. As long as the decision to test or not to test is based on sound medical judgement, rather than cost-cutting considerations, this is a healthy development.

27. **MANY PROBLEMS WITH MEDICAL TESTS ARE ATTRIBUTED TO USER ERROR. WHAT ARE MANUFACTURERS DOING TO MAKE TESTING EQUIPMENT MORE USER FRIENDLY?**

Manufacturers strive constantly to make tests easier to perform and easier to read. Often this involves extensive research and cooperation with the Food and Drug Administration. For example, there is now an effort underway to study how to make home glucose monitoring devices easier for diabetics to use. Manufacturers conduct research on the human factors influencing the performance of tests and offer training programs and service contracts for their products. Many have staffed telephone lines to help solve any problems and will make "house calls" to make sure everything runs smoothly. In other words, manufacturers share responsibility for the generation of quality information with their customers.

BENEFITS OF TESTS

28. **WHAT GOOD HAVE MEDICAL TESTS DONE?**

Medical tests are an essential part of modern health care. They have saved countless lives and untold pain and suffering. Tests routinely screen babies for the preventable mental retardation of PKU. They identified the viruses that caused the "blue baby" syndrome and helped scientists devise a preventive treatment.

Glucose monitoring allows diabetics to lead more normal lives. AIDS screening has made the blood supply safe again. Millions have been saved from blindness by glaucoma testing. Pap smears have reduced death from cervical cancer and occult blood tests have cut down on fatal cases of colon cancer. Cholesterol testing is encouraging people to cut their risk of heart disease. In the diagnostic imaging field, mammography allows us to detect breast cancer before it becomes deadly. In many cases, medical tests and diagnostic imaging have also saved the risk and expense of exploratory surgery.

3/2/88
3:15 p.m.

INTERNATIONAL SOCIETY
FOR
CLINICAL LABORATORY TECHNOLOGY
Suite 918, 818 Olive Street St. Louis, Missouri 63101 (314) 241-1445

Statement of the International Society for
Clinical Laboratory Technology
St. Louis, Missouri
On the Federal Government's Role in
Ensuring the Quality of Medical Laboratory Testing
Before the Oversight of Government Management Subcommittee
Senate Committee on Government Affairs
The Honorable Carl Levin, Michigan, Chairman
The Honorable William S. Cohen, Maine, Ranking Minority Member
March 24, 1988

The International Society for Clinical Laboratory Technology (ISCLT) is a national professional association representing over 7,000 medical technologists (RMTs) and laboratory technicians (RLTs) across the United States. Mr. Chairman, we appreciate the opportunity to share our comments with you and the Committee on the role of the federal government in ensuring the quality of clinical laboratory testing.

Uniformity of Requirements

A clinical laboratory test, regardless of where it is performed, requires quality assurance. Internal quality control, proficiency testing, inspections, recordkeeping and personnel requirements are all important in assuring quality laboratory services. These requirements should apply to laboratory testing in all settings, including physicians office laboratories (POLs), free standing ambulatory care clinics, hospital wards, health fairs, and public screening programs.

For too long the clinical laboratory industry has operated with an array of standards based on setting. For example, under the Medicare regulations, independent clinical laboratories have specific requirements for quality control, personnel, inspections, recordkeeping and proficiency testing; hospital laboratories do NOT have personnel regulations (except director); and POLs, ambulatory clinics, hospital wards, etc. do not have any laboratory regulations. ISCLT emphatically believes that federal regulations ARE necessary, and that they have improved the quality of clinical laboratory services.

Personnel Requirements

The most important element in clinical laboratory testing is the individual who collects, transports, labels, stores, and prepares specimens for testing, as well as the individual who performs the testing, calibrates the instruments, records and reports the results, validates the laboratory methods and procedures, and prepares, stores, and monitors the reagents. It is absolutely essential that clinical laboratory personnel be properly trained to fulfill these functions.

The problem with most personnel requirements is that they are written to protect the interests of the profession being regulated, rather than the public. Unnecessarily restrictive personnel requirements limit entry into the field thereby creating artificial labor shortages and restricting mobility within the profession. In the case of the clinical laboratory industry, the Veterans Administration and Medicare have established an artificial barrier to advancement for U.S. military-trained laboratorians. Graduates of the U.S. military training schools fulfill the duties of medical technologists while in the armed forces, but are not permitted to do the same by the Veterans Administration and Medicare once they enter the civilian workforce.

In the case of the Veterans Administration, the decision not to recognize military-trained technologists is arbitrary and in direct opposition to a settlement agreement signed by ISCLT and the U.S. Office of Personnel Management (OPM). Why, we ask, are military-trained technologists qualified to provide technologist-level laboratory services to U.S. servicemen, but NOT qualified to do the same for veterans? The reason is "turf" protection by certain groups of laboratorians promoting exclusive four-year college degree requirements for technologists and general supervisors.

ISCLT does not believe that an exclusive four-year college degree requirement (or equivalent) for technologists/supervisors is warranted. This does not mean that ISCLT opposes four-year college training programs, but that a baccalaureate degree should not be the only route for qualifying as a technologist or general supervisor. Many thousands of clinical laboratorians have obtained adequate training without earning a four-year college degree. These individuals are trained in a variety of settings including the U.S. military, specialized laboratory training schools, junior colleges, and through a combination of formal training and on-the-job experience. The Medicare program recognized this fact in the 1970's by embracing the concept of "alternate routes" to formal college degree requirements. Inclusion of "alternate routes" is also a membership requirement (Category A) of the National Commission for Health Certifying Agencies, a standard setting organization for health certifying agencies established with the aid of substantial sums of money from HHS.

By order of Congress, an "alternate route" for medical technologists/general supervisors was implemented by Medicare in 1975. The "alternate route" consisted of a job-related, competency based examination, referred to as the HHS Proficiency Examination. The HHS Proficiency Examination has been administered seven times since 1975 to 65,576 individuals, with 30,779 having passed (46.9%). The HHS Proficiency Examination was developed with input from all sectors of the industry (including organizations promoting the exclusive four-year college requirement). A widely respected and experienced testing organization, the Professional Examination Service (PES), developed and administered the examination. The HHS Proficiency Examination was pre-tested against four-year college graduates, and statistics from the examination consistently showed that the examination was quite difficult, even for the four-year college graduates who challenged it. In addition, a validation study commissioned by HHS concluded that passing the HHS Proficiency Examination correlated with on-the-job performance.

The HHS Proficiency Examination is the only "alternate route" available under the Medicare regulations, and it has been a valuable means for individuals who do not have a four-year college degree to demonstrate their ability to qualify as medical technologists and general supervisors. ISCLT is distressed that a member of the United States Senate is attempting to eliminate the HHS Proficiency Examination. We urge you, in fairness to our military-trained laboratorians and others, to continue the HHS Proficiency Examination as an "alternate route" for qualifying under the Medicare, and other, federal regulations. If the purpose of this committee is to improve quality and contain costs, then the concept of career ladders through alternate routes by utilization of the HHS Proficiency Examination is a must. In 1987, over 7,500 individuals challenged the HHS Proficiency Examination, and approximately one-half passed, all at no cost to the federal government.

ISCLT is also concerned over a worsening shortage of qualified medical technologists which has developed over the past several years. In some areas of the country, such as New York City and the northeastern seaboard, the shortage is reaching crisis proportions. Failure to require federal government agencies to develop "alternate routes" for qualifying medical technologists will only serve to prevent qualified individuals from providing essential clinical laboratory services.

The Role of Private Accrediting Agencies

Private accrediting agencies serve an educational role. However, these organizations are not designed to be regulatory agencies. Granting "deemed" status to private accrediting agencies is tantamount to the federal government surrendering its regulatory enforcement authority, and ISCLT therefore opposes granting "deemed" status to private accrediting agencies.

MEDICAL GROUP
MANAGEMENT
ASSOCIATION

STATEMENT
OF THE
MEDICAL GROUP MANAGEMENT ASSOCIATION
ON THE
FEDERAL GOVERNMENT'S ROLE IN ASSURING THE QUALITY OF MEDICAL LABORATORY TESTING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS

April 21, 1988

CENTER FOR RESEARCH IN AMBULATORY
HEALTH CARE ADMINISTRATION

EXECUTIVE OFFICE
1355 S. Colorado Blvd. • Suite 900
Denver, CO 80222
303-753-1111

AMERICAN COLLEGE OF
MEDICAL GROUP ADMINISTRATORS

MEDICAL GROUP MANAGEMENT ASSOCIATION
STATEMENT ON CLINICAL DIAGNOSTIC TESTING

The Medical Group Management Association (MGMA) is pleased to submit these views for the record of the subcommittee's hearing on the quality of medical laboratory testing.

MGMA, headquartered in Denver, Colorado, is the nation's oldest and largest association of medical group practices, representing more than 3500 groups throughout the United States, in which more than 78,000 physicians practice. MGMA members range from the nation's largest multi-specialty clinics to small practices of only a few physicians.

Approximately 70 percent of MGMA member groups have some in-house laboratory capacity. While virtually all of these would be characterized as "physician office laboratories," they represent a broad spectrum of clinical diagnostic capabilities, ranging from large pathology departments (fully equipped to do the entire range of diagnostic work and staffed with highly trained personnel) to very limited laboratories performing only routine and relatively simple tests, many of which can be done without extensive equipment or personnel. In the former case, these "full service" group practice laboratories do not only diagnostic work for the patients of the group, but may also do referral work for other physicians in the community, and in some instances, have such highly sophisticated and esoteric testing capabilities as to do referral work for other physicians on a national and even an international basis. **Many of these larger laboratories already meet Medicare conditions of participation.** At the other end of the spectrum, the group practice laboratory would do only the most basic tests for its own patients, sending more complicated work out on a referral basis to a commercial, hospital, or larger group practice laboratory.

MGMA hopes that as the Subcommittee evaluates the current regulatory system applicable to clinical laboratories at both the state and federal level, it will understand and appreciate the diversity of current arrangements contained within the broad category referred to as physician office laboratories.

Federal Regulation of Clinical Diagnostic Laboratories

Clinical laboratories have been the focus of considerable Congressional interest in recent years. In 1984, as part of the Deficit Reduction Act, Congress revised the Medicare methodology for diagnostic laboratory services, putting payment on the basis of a fee schedule for both independent and physician office laboratory work. That same legislation commissioned the Secretary of the Department of Health and Human Services to study physician office laboratories with an eye towards possible application of federal standards. The Department's report, due in April of 1987, has not yet been issued.

In 1986, as part of the Consolidated Omnibus Budget Reconciliation Act, Congress again amended Medicare payment rules to limit the fee schedules as payment in full for laboratory work done in physician offices, effectively mandating assignment on all Medicare laboratory work. This provision which MGMA opposes, became effective January 1, 1987.

Most recently, in the Omnibus Budget Reconciliation Act (OBRA) of 1987, without awaiting the Department's study results, the Congress required Medicare to regulate all physician office laboratories performing more than

5,000 tests per year, setting such standards "as the Secretary may require." This provision becomes effective on January 1, 1990. The legislative history of the 1987 amendment indicates that it is directed at "high volume" physician office laboratories, and suggests that the licensing standards for such physician office laboratories be the same as those now applied to independent laboratories under Medicare conditions of participation.

The 1987 OBRA requirement, like its COBRA predecessor, was added to the bill in conference without hearings or debate in either House of Congress. Affected medical groups had no opportunity to comment on its merits prior to adoption, or to suggest more appropriate ways in which quality testing results in physician office laboratories could be assured. The result was **bad legislation--an arbitrary and inflexible solution to a complicated problem.** We applaud the Subcommittee for opening up this issue for a public hearing, and trust that any legislative recommendations resulting from the hearings will similarly be conducted in open proceedings with opportunity for input from affected interests.

Complexity of Physician Office Laboratory Testing

Since the average physician orders over 2,000 tests per year, the 1987 OBRA provision which regulates all physician office laboratories doing in excess of 5,000 tests per year will require regulation of virtually all group practice laboratories. The 5,000 tests threshold is not, contrary to the legislative history, evidence of "high volume". Nor does it bear any rational relationship to the complexity of the laboratory work performed in a particular office. As a result, it could well produce both under regulation and over regulation at the same time. A laboratory doing 4,000 sophisticated tests--HIV for example, where erroneous results would have very severe consequences to patients--would be unregulated, whereas another lab doing 100,000 relatively simple blood or urine tests would be subjected to the entire panoply of current standards that would not be necessary to assure quality and proficiency in the laboratory operation.

Despite the defects in the OBRA approach, MGMA is not opposed to an appropriate federal role in the oversight of physician office laboratories. Indeed, our members believe that their laboratory operations should meet the same high standards of practice to which they adhere in other aspects of their practices. Accurate laboratory testing plays an integral role in delivering the high quality patient care to which physician group practices are committed. In fact, neither the Congress not the Department of Health and Human Services has come forward with any significant body of evidence that suggests that there are serious quality assurance problems peculiar to physician office laboratories. Ironically, many of the testing errors which have been highlighted in recent Congressional testimony, or in the press, originated in independent commercial laboratories already subject to federal standards.

If Congress requires federal regulation of physician office laboratories, MGMA would support a program which differentiates between and among laboratories based on the types and complexity of the testing performed, not simple volume calculations. Thus, where automated testing equipment performs high volumes of relatively routine tests, quality assurance, proficiency testing, and equipment maintenance requirements might well be appropriate, whereas personnel credentialing requirements would not. In contrary situations, where even small volumes of very complex tests require highly trained personnel, credentialing requirements may be appropriate.

MGMA is particularly opposed to any blanket application of personnel standards to physician office laboratories simply because they are currently applied to large commercial laboratories. In some geographic areas, the supply of laboratory technologists is not sufficient to staff every physician office now doing clinical testing. To require physicians to hire such personnel where their expertise is not specifically required would aggravate the existing shortage situation--not unlike the nursing shortage- and drive up the cost of operations, and thus ultimately the costs to patients and insurers, in commercial and physician office laboratories alike.

The unavailability of particular credentialed personnel in some parts of the country might well force some laboratories to close, or restrict their operations, even where the laboratory had no demonstrated quality assurance problem. It is important to note that maintaining a laboratory capability within a physician's office provides a variety of benefits to both the physician and the patient. Without relatively simple hematology testing in the office, for example, the physician could not adequately care for common emergencies such as appendicitis or intestinal bleeding. Readily available testing results allow more timely diagnosis, and where necessary, earlier treatment resulting in better patient outcomes.

There is also a significant convenience feature for the patient whose laboratory work is done on site. In some instances this prevents the need to travel to a separate site for testing, or to schedule a second office visit after test results are in. It also allows the attending physician more direct control over the quality of laboratory work, including the ability to do repeat testing in one office visit where first results are inconclusive or further testing is otherwise indicated.

Thus, while MGMA supports effective quality control in any laboratory setting, we urge deliberation in the application of federal requirements which may have no real payoff in assuring quality, but would have the predictable consequence of making in-office testing less available and less affordable.

Regulation based on complexity rather than volume would place priority in those areas where the need and potential payoff from regulation are the highest, and would target personnel, survey and inspection resources in a more efficient manner.

State and Private Sector Models

Any new federal regulation of physician offices should build upon existing state and private sector models. One state model which MGMA believes constitutes a good example is that used by the Commonwealth of Pennsylvania. Pennsylvania divides physician office laboratories into three levels. The lowest level is for those laboratories performing only simple tests, and that accounts for 56 percent of the labs in Pennsylvania. These laboratories register and comply with state quality control requirements, but are not overly burdened by personnel, survey or inspection rules. A second level, performing more complex tests, is also subject to proficiency testing. Level-three laboratories are subject to more complete requirements similar to the Medicare conditions of participation for independent laboratories. Other states have developed innovative and cost effective approaches as well, which any federal program should permit to continue.

MGMA also urges the Congress to review carefully existing private sector accreditation programs and those under development. Any federal standards developed should be written in such a way that the equivalent assurances from a private sector accrediting body could substitute for federal or state certification. The federal government has used the "deemed status" approach in many regulatory areas for many years, and its advantages in terms of cost and administration are well known.

For example, **the Accreditation Association for Ambulatory Health Care (AAAHC) has run an accrediting program for physician group practices since 1979.** Many MGMA member groups are currently accredited by AAAHC, whose standards for pathology and laboratory services already require a number of the elements under discussion at the federal level, including documentation of appropriate quality assurance, calibration of equipment, and validation of tests through standardized controls.

Other private sector initiatives like the **Commission of Office Laboratory Assessment are** underway, and the Congress should encourage their development so that whatever laboratory regulation is ultimately required can be implemented to the maximum extent possible through private sector, physician-directed organizations. It is clear that the federal agencies, as well as those in some states, do not have the current budgetary and manpower resources to do an effective job of laboratory regulation if asked to take on the entire universe of physician office laboratories. "Deemed status" for private sector accrediting bodies may well be the only way in which new quality assurance mechanisms can be put in place rapidly.

The Need for an Adequate Transition

Should the Congress conclude that further regulatory requirements are necessary for physician office laboratories, **MGMA urges Congress to build adequate lead time into the regulatory process.** In recent years, physician practices dealing with Medicare patients have absorbed an enormous number of legislative and regulatory changes which have vastly increased the complexity of doing business under the federal insurance program. This will be particularly true in the case of clinical laboratory services. While much is being done and in place already, if new federal standards are superimposed, group practices will need adequate time first to be educated about the new requirements, and then to make appropriate adjustments to satisfy them. This will be particularly true where application and review processes are involved, or if on-site inspections are necessary.

Summary

In summary, the Medical Group Management Association applauds the Subcommittee's efforts to better understand the nature of laboratory testing, and the appropriate role, if any, of further regulatory efforts. We urge the Subcommittee to take a deliberate look at the problem with adequate opportunity for public involvement. If legislative recommendations result, **we urge (1) regulation based on complexity of testing, not volume of testing; (2) appropriate role for private sector accreditation; and (3) adequate lead time to implement new requirements.**

MGMA would be pleased to work with the Subcommittee and its staff to ensure that clinical diagnostic laboratory services provided in the nation's group practices meet reasonable standards which insure the quality and itegrity of test results.

For further information contact:

Kathleen Konka, MGMA Government Relations Director
303/753-1111, or

Robert J. Saner, MGMA Washington Counsel
202/659-2900.

AMERICAN SOCIETY OF CYTOLOGY

PUBLIC AWARENESS/STUDENT RECRUITMENT COMMITTEE

January 6, 1988

The Honorable William S. Cohen
United States Senate
Washington, D.C. 20510

Dear Congressman,

From the article "Clinical-Lab Test Studied by Panels in House, Senate", Wall Street Journal, December 16, 1987 and from speaking to Walt Bogdanich, the author, I am aware that in the coming months your committee will be pursueing investigations into clinical laboratory practices. I am particularly interested in regulations pertaining to cytotechnology (cytology testing - Pap smears).

The purpose of this letter is not to comment on the series of articles on Pap smear testing which appeared in the Wall Street Journal, but to alert your committee to the critical shortage of certified cytotechnologists. Due to the drastic decline in the number of accredited Schools of Cytotechnology, the decrease in student enrollment (in all of the allied health professions) and the increased utilization of diagnostic cytology for the detection and documentation of cancer and precancerous lesions, there is a growing shortage of qualified cytotechnologists.

Prior to 1970, Schools of Cytotechnology were financially supported (in part) through the Department of Health, Education and Welfare's Cancer Control Program. At that time there were 118 accredited Schools of Cytotechnology with an approximate capacity of 600 students per year.

Since the discontinuation of the Cancer Control Program in 1970, there has been a steady decline in the number of accredited cytotechnology programs. Current figures place the number of active Schools of Cytotechnology in the United States at 43. Additionally, only 60-70% of student positions in these programs are filled. Nationally, the result of this decline is that there will be only 170-215 new graduates for the 1987-88 academic year.

The American Society of Clinical Pathologists (ASCP) reports that since the inception of the national certifying exam for cytotechnologists in 1957, there have been approximately 9,000 cytotechnologists certified. It is estimated that 70-80% of those registered are actively working in the field. Using the conservative figures of 7,000 working cytotechnologists and 215 current students, new graduates will make up only 3% of the work force. If we do not increase this percentage, we will not be able to fill positions created by technologists retiring, leaving the field to pursue other career options and to fill new positions due to the current growth in the field.

Cytotechnology is a field of laboratory science that the general public knows little about. The most recognized test done in a Cytology Department is the Pap smear. However, it is only one of the cancer detection test we perform. Unfortunately, it is the one which is most susceptible to the practices of a large "pap factory" as has been reported, Wall Street Journal, November 2, 1987.

Because of the continuous improvement in collection techniques, cytotechnologists evaluate cellular samples from all body sites. Palpable and radiographically visible masses in the lungs, breast, thyroid, liver, pancreas, kidney, prostate etc. may be sampled and evaluated for the presence of cancer or precancerous lesions. Fine needle aspiration cytology may be performed on an outpatient basis. This testing may in fact preclude the need for a diagnostic surgical procedure. Aspiration cytology is far less traumatic for the patient and considerably less expensive. This type of cytology testing is, for the most part, done in hospital laboratories which are accredited by the Joint Commission on the Accreditation of Hospitals (JCAH), the College of American Pathologists (CAP) and fall under CLIA regulations.

In November the American Society of Cytology (ASC), approved the formation of a Public Awareness/Student Recruitment Committee. The purpose of this committee is to assist the Schools of Cytotechnology to improve their recruitment materials and methods, to pursue avenues to increase public awareness regarding careers in cytotechnology and to investigate funding sources for recruitment activities, program support and student scholarships.

As chairman of this committee, I would urge you to consider this recruitment problem and the lack of funding for program support when your committee contemplates laboratory regulations and associated issues. Whatever regulations are enacted, we as a profession need to be able to recruit qualified individuals to pursue careers in cytotechnology (and all of allied health) in order to be able to supply the quality of health care you are seeking to insure.

If your committee is interested in further information regarding student recruitment in cytotechnology, I would hope you would call upon my committee for assistance. I can be reached at: Medical Center Hospital of Vermont, Cytopathology Department - D.U., Burlington, Vermont 05401, (802) 656-5132.

Sincerely,

Jacalyn L. Papillo

Jacalyn L. Papillo, CT(ASCP)
Chairman, Public Awareness/Student
Recruitment Committee

cc: James E. Parker, M.D., President ASC
Walt Bogdanich, Wall Street Journal

STATEMENT SUBMITTED BY
METPATH, INC.
TO THE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
COMMITTEE ON GOVERNMENTAL AFFAIRS
APRIL 21, 1988

INTRODUCTION

MetPath, Inc., a wholly-owned subsidiary of Corning Glass Works, is an independent clinical laboratory providing a broad range of diagnostic testing services for the prevention and treatment of disease. Through a network of service centers and regional facilities, we serve physicians, industrial organizations and hospital clients. Our capabilities include more than 1,200 routine and esoteric tests, therapeutic drug monitoring, radioimmunoassays, immunochemistry, tissue pathology and cytogenetics, chemistry, microbiology, serology, virology and hematology. MetPath is licensed pursuant to the Clinical Laboratories Improvement Act and is certified to accept reimbursement from Medicare. We are a member of the American Clinical Laboratory Association ("ACLA"), the National Committee for Quality Health Care and the Alliance for Aging Research.

Recognizing that quality health care largely depends upon quality diagnostic information, we understand the Subcommittee's concern regarding the reliability and accuracy of laboratory performance. Recent media reports have chronicled the sometimes devastating consequences of faulty test results, and we applaud your efforts to meaningfully address this important issue. MetPath, as a member of ACLA, fully concurs in the ACLA statement delivered before the Subcommittee on March 24 -- all clinical laboratories (physician office, hospital, intrastate and interstate independents) should be subject to governmentally mandated and enforced uniform, comprehensive quality assurance regulations. We would, however, like to take this opportunity to respond to several points raised by the testimony of other witnesses during the hearings.

THE PAP SMEAR CONTROVERSY

Allegations of high false negative rates in pap smear testing are especially alarming since, when adequate specimens are analyzed correctly, the test is highly effective in the early detection of cervical cancer. Several witnesses have suggested cytotechnologists' oppressive workload as the leading cause of false negative results. Accordingly, some have advocated the imposition of workload limitations (e.g., restrictions upon the number of cases or slides that can be reviewed per day or per year) as a means of improving cytotechnologists' performance.

MetPath does not dispute that overwork and fatigue can lead to errors. However, the fact remains that many licensed and talented cytotechnologists can exceed recommended limits without compromising quality, while other cytotechnologists -- observing the same limits -- are known to err frequently and, in the absence of improved regulation, will continue to endanger the public. The scientific literature is consistent with these observations. The literature reveals no correlation between cytology false negative rates and workload limitations. In fact, among the few laboratories that have publicly released false negative rates, those showing high false negatives were operating approximately within the American Society of Cytology ("ASC") recommended workload guidelines!

For example, Duke University Medical Center recently reported a false negative rate, major category, of 16 percent between 1983 and 1987. Since the Duke laboratory received ASC accreditation in 1973, its cytotechnologists were working within the ASC-recommended 12,000 case per year limitation during this period. In another study involving the Duke laboratory, a re-review of cases from 1974 revealed false negative rates of 40 percent or higher. Obviously, in the intervening years (1975-1982), improvement would have been attributable to factors _other than_ changes in workload limitations.

Studies of positive pick-up rates (_e.g._, the detection of cervical abnormality) at 10 U.S. Air Force cytology laboratories (1980-87), where workload limits of 75 slides per day were enforced, are also instructive. The pick-up rates, shown to correlate inversely with false negatives, ranged from one-and-one-half to six percent, worst lab to the best. Clearly, the workload limitation did not preclude poor performance in the "worst lab." Dramatic improvement in the pick-up rates and reduced inter-laboratory variability were documented between 1980 and 1983; the authors attribute these changes to an intensive education program -- not to any workload adjustments.

And, at the most recent ASC annual meeting, the false negative rate data from the Mayo Clinic demonstrated improvement during a span of eight years. Workload limitations were never even discussed -- rather, the improvement was attributed to increased emphasis on quality control and thoroughness in re-reviewing cases.

These examples represent documented experience at three important cytology centers. In addition, MetPath's experience also supports the premise that false negative rates do not correlate with workload levels in an environment where quality controls and continuing education are in force. We would be pleased to share our data with the Subcommittee, if that would be helpful.

Underlying these data is our concern that, by imposing cytology workload limitations, Congress may be lulled into a false sense of security that the pap smear "crisis" has been adequately dealt with. We believe that, in fact, such action would only exacerbate certain quality and production problems that presently exist.

First, a federally mandated workload limitation -- by necessity, arbitrarily determined -- fails to take into account the varying degrees of experience and expertise among cytotechnologists. In addition, mandated limits -- which, in effect, assume that all cytotechnologists perform at the same level -- will aggravate the current industry-wide shortage of qualified personnel. A workload limitation, by forcing many cytotechnologists to work below their capacity for reliable testing, will therefore needlessly (and, in some cases, dangerously) prolong the turn-around time for pap smears. Congress must recognize that cytotechnologists are skilled professionals capable of determining their own capacity for safe and accurate work, and that laboratory directors must be accountable for establishing stringent quality control environments.

Second, a workload limitation would be detrimental to patients by encouraging physicians -- anxious to avoid higher costs and increased processing time arising from laboratory backlogs -- to submit "one slide cases", even though several slides per patient may be clinically necessary or desirable.

Third, enforcement of workload limitations would be extremely difficult. The current shortage of cytotechnologists has already led to widespread "multiple jobbing". Cytotechnologists, having completed their review of "allotted" slides at one laboratory, will increasingly seek "new" work at another facility, which would have no feasible means to determine whether the cytotechnologist has already examined the allowable daily "quota" of slides.1/

MetPath believes that patients would be far better served by several more meaningful alternatives, most of which were alluded to during the hearings. These include: a prohibition against so-called "piecework", whereby cytotechnologists' primary form of compensation is on a per slide basis; a prohibition against reviewing slides in other than a laboratory setting; mandated continuing education requirements for all cytotechnologists and for physicians involved in taking and analyzing pap smears; mandated error-rate measurement of all cytotechnogists; federal financial support for cytotechnologists' training and education; and laboratory proficiency testing and on-site evaluation. We urge that Congress extend such requirements to every U.S. laboratory which provides pap smear testing.

Finally, one of the most effective assurances of quality testing would be the enactment of a national direct billing law. Too frequently we have we heard that a physician's ability to maximize mark-up on laboratory services dictates that physician's choice concerning where such testing will be done. It is imperative that

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1/ For further elaboration of MetPath's position on workload limitations, see Attachment I -- our response to the Recommended Guidelines for Cytology Laboratories recently proposed, in draft form, by the American Society of Clinical Pathologists.

quality, not personal profit, be the sole determinant when a physician selects a laboratory. Yet, that objective will continue to be undermined until a national direct billing law is enacted. As Herbert W. Dickerman, M.D., Ph.D., Director of the Wadsworth Center for Laboratories and Reserach of the New York State Department of Health told the Subcommittee on March 23, 1988: "... a national direct billing law, similar to New York's, which requires that laboratories bill the patient or the insurance carrier rather than the physician, would eliminate incentives to choose laboratories based on cost considerations, and would assure that the public knows where tests are actually performed."

QUALITY DISCLOSURE

MetPath strongly supports the disclosure of proficiency testing results -- both to physician "customers" as well as to the general public. We believe that this information is relevant, and indeed, necessary, to the responsible selection of laboratory services. The ready availability of this information (perhaps through the Department of Health and Human Services or some other central repository) to health care consumers will encourage a more participatory role for patients and, accordingly, increased accountability for physician choice. In addition, the federal government, through disbursement of Medicare and Medicaid funds, presumably also has an interest in knowing the performance levels of those laboratories serving program beneficiaries.

We appreciate this opportunity to share our views. If further information would be helpful to the Subcommittee, we would be happy to provide it.

ATTACHMENT I

MetPath

MetPath Inc
One Malcolm Avenue
Teterboro, New Jersey 07608
201-393-5464
201-393-5000

a CORNING Clinical Laboratory

S. Raymond Gambino, M.D.
Executive Vice President and
Chief Medical Officer

April 6, 1988

George F. Stevenson, M.D.
Senior Vice President
American Society of Clinical Pathologists
2100 West Harrison Street
Chicago, Illinois 60612-3798

Dear George:

Thank you for sending me the DRAFT copy of ASCP's "Recommended Guidelines for Cytology Laboratories." In addition to my comments, I have attached a memo to me from Dr. Paul Krieger, Chief of Anatomic Pathology at MetPath/Teterboro, on the subject of workload limits.

- In general, the recommended guidelines are excellent. But I do have a few critical comments to make--specifically in regard to the workload limits suggested for cytotechnologists.

- I do not deny that there are indeed limits to the number of slides and cases one cytotechnologist or pathologist can process accurately in one day. For example, if someone said they could run a two-minute mile you would know it was not possible. On the other hand if someone said that no one should run a mile faster than 10 minutes--in order to prevent heart attacks--you would also know that something was wrong. Why? Because we have factual data on which to base guidelines.

- There are, however, no factual data to support the specific workload limits recommended by the ASCP Cytopathology Council. Specifically, no one has ever published a scientific study to show that if you process more than 40 cases a day your error rate goes up and that if you keep under 40 cases a day your error rate will be low. In fact, most directors know of cytotechnologists who screen slowly and make numerous errors!

- Over the past ten years Dr. Paul Krieger, Chief of Anatomic Pathology at MetPath/Teterboro, has developed a superb Q.C. program. He knows the false negative fraction for each technologist in his laboratory. He knows at what workload level each technologist begins to fail. The difference among technologists is at least a factor of three with the upper limit at 140 gynecologic cases per day.

- His laboratory has an outstandingly low false negative fraction--4.7 percent for 1987. This rate is far lower than that reported by the few published studies on error rates from highly reputable laboratories that operate with workload limits. (See attached memo, dated 3/23/88, from Dr. Krieger to me).
MetPath/Teterboro's low false negative fraction was corroborated recently in a

TV broadcast in which the results of NY State's Cytology Proficiency Test for four private laboratories were compared. Lab No. 1 missed one cancer out of 7, and failed. Lab No. 2 missed one out of 14. Lab No. 3 missed one out of 17. Lab No. 4--MetPath/Teterboro--missed one out 27.

- MePath/Teterboro's low false negative fraction is attributable in part to the following:

1. Superb supervision by staff of 5 full time pathologists and 7 cytotechnologist managers.
2. Excellent semi-private work areas for each cytotechnologist.
3. Excellent equipment
4. Continuing education--weekly, accredited by ASCP.
5. Use of TV monitors to demonstrate interesting and instructive cases to all.
6. Superb QC program. All repeat cases screened by rotating teams of staff with supervisor's license. Cases selected on basis of random number table. The error rate tallies are maintained in several categories.
7. Cytotechnologists pace themselves in the context of the strict QC environment.
8. No part time work.
9. No work taken home.
10. All staff fulltime salaried.
11. No minimum number of cases required per day.
12. We do provide piece work bonus pay for cytotechnologists on a voluntary basis--if their QC performance is satisfactory.
13. Dr. Krieger has discharged cytotechnologists with high error rates.

- I also question the slavish adherence to 10 percent repeats. The confidence limits of any sampling program are defined by the size of the sample--not by the size of the population being studied. Thus, a sample of 1000 gives you the same confidence interval for 10,000 cases as it does for 100,000 cases. The problem with 10 percent is that most small labs will never have a large enough sample to provide them with reliable confidence intervals from month to month. Thus, they will not be able to detect changes in error rates from month to month. What is required is an absolute minimum number of repeats--not simply 10 percent.

- A major root cause for poor work in cytology nationwide is the low price certain laboratories, that take short cuts, charge for the service. We know of laboratories charging $1.95. This low price is then marked up to patients. I know of one pathologist who is forced to charge a maximum of only $3.95 in order to remain competitive. He can't afford glass cover slips! Our experience tells us that patient billing is an answer to this problem. This eliminates the practicing physician as economic middleman between patient and laboratory, and eliminates physician markup of laboratory services. The ASCP guidelines, by not addressing the issue of laboratory income sufficient to meet the standards, fail to focus our attention on a most important factor behind our failure in this area.

- Finally, ASCP must focus national attention on the inadequate number of schools for cytotechnologists. For example, in the state of Colorado there isn't one school for cytotechnologists. This is another major root cause for the quality problems we have in cytology. MetPath/Teterboro is sponsoring five scholarships at the New Jersey College of Medicine's school for cytologists. ASCP should not address laboratory guidelines without addressing educational guidelines. There can be no quality without training. Too many Americans believe that you can inspect and regulate quality into a product. It just doesn't work that way.

George, these guidelines should NOT be accepted just as is. If ASCP engraves workload limits into their guidelines they will fossilize a number not related to reality. Further, such an approach fails to consider changes in technology. For example, future probe technology, or computer technology, or both, may permit much faster screening. Also, it is too simplistic to simply say that Gyn cases can go to 12,000 per year and non-Gyn only to 3,000. Some non-Gyn cases may take more time and some less. Again, for example, screening urinary cytology utilizing DNA analysis for ploidy may alter significantly the number of cases that can be screened.

Finally, thank you again for providing me with the opportunity to make comments that will forwarded to the Board of Directors.

Sincerely,

Ray

Ray Gambino, M.D.

cc: Paul Krieger, M.D., Joseph O'Brien, M.D., Andrew Baker, Kirby Hannan

Testimony of

TECHNICON INSTRUMENTS CORPORATION

presented by

Mr. James A. Edlund
President and Chief Operating Officer

and

Kenneth D. Noonan, Ph.D.
Senior Vice President of Business Development
and Technology Assessment

regarding

Reliability of Laboratory Testing and

Efficacy of Federal Oversight of the Clinical Lab Industry

before the

Subcommittee on Oversight of Government

Management of the Senate Committee on Governmental Affairs

March 23 - 24, 1988

Technicon Instruments Corporation ("Technicon") is a principal U.S. manufacturer of in vitro diagnostic blood analyzers. It is a privilege to submit this testimony to the Senate Governmental Affairs Subcommittee on Oversight of Governmental Management as the Subcommittee investigates the reliability of clinical lab testing and the efficacy of federal oversight of the lab industry.

Technicon, founded in 1939 and headquartered in Tarrytown, New York, is a wholly owned subsidiary of The Cooper Companies, a Palo Alto based health care corporation. Technicon, and other manufacturers of highly automated clinical laboratory equipment, share the concerns of the Subcommittee regarding recent reports of inaccurate clinical laboratory testing. In order to fashion effective remedies to the problems described in the press and at recent Senate hearings, it is imperative that public policymakers and regulators comprehend the unique role which manufacturers play in the process through which human illness is diagnosed. In particular, it is important that the Subcommittee appreciate the remarkable strides which companies like Technicon have achieved in automating diagnostic systems to ameliorate the possibility of human error in testing. As one of the leaders in developing and marketing automated test systems, Technicon believes that many of the problems identified in the Subcommittee's hearings can be alleviated through enhanced automation as well as through modest changes in federal and state regulatory authorities. It is in this spirit that we offer our views regarding these important issues.

Technicon participates in the clinical chemistry segment of the in vitro diagnostics marketplace through a broad line of instrument/reagent systems which it both manufactures and distributes including the SMAC, CHEM-1, RA-family and Assist clinical chemistry analyzers. In the hematology segment, Technicon manufactures and distributes both the H*1 and H-6000 product lines. In fiscal 1987, Technicon reported revenues of $469,000,000, with its revenue coming primarily from clinical chemistry and hematology products.

Technicon's primary customers are the hospital and reference laboratory segment of the clinical laboratory market, although Technicon recently introduced the highly automated Assist clinical chemistry analyzer which is intended to serve the group practice segment of the physician's office marketplace. This instrument incorporates many of the features of automation frequently associated with systems installed in the hospital and reference laboratory. Technicon's primary corporate presence is in the automation of clinical lab tests. Technicon does not distribute tests such as the PAP test, which, to date, have not proved amenable to automation.

Production of Instruments and Chemical Reagents

Technicon designs and manufactures diagnostic instruments (blood analyzers) as well as the chemical reagents which are pumped through the instruments, enabling them to analyze blood. Technicon, and other manufacturers of automated systems, subject all the components of the systems to extensive quality control measures to assure the highest quality product.

Technicon's personnel qualifications assure that specialized staff participate in the production of all instruments and reagents. Manufacturing engineers, chemical engineers, technicians, and assemblers work under the guidance of specialized production supervisors who monitor every stage of instrument and reagent production.

Technicon manufacturing facilities have extensive in-house quality control programs. Instrument quality assurance measures include the following:

1. Upon receipt of a component part for the instrument, Technicon inspects the part and checks it against drawings and specifications for accepted quality level standards of industry acceptance.

2. All parts are compiled into a kit and issued to the shop floor where the instrument is assembled to product specification.

3. Materials are inspected at every stage of development, and are stamped and dated so that permanent records are preserved for each instrument which detail the assembly process and the quality assurance measures performed at each stage.

4. Once fully assembled, the product is sent to final test areas and put through an elaborate test protocol to ensure full functioning of the instrument; modifications are made if necessary.

Reagent quality assurance measures include:

1. All raw material components (e.g. chemicals, biologicals, glass vials, stoppers, etc.) are tested against set specifications prior to their use in finished product production.

2. Raw material components are then transferred to production where additional testing and inspections are performed. The manufacturing facility is

designed with special areas for the production of reagents which incorporate raw materials that require a controlled environment in production (e.g. low relative humidity atmosphere or HEPA-filtered air).

3. If the reagent meets all specifications, it is "assembled" in batches with distinct lot numbers. The reagent containers are labeled with such items as reagent name, lot number, and expiration date. Random samples of the batch are tested in a quality control lab using both Technicon and competitor's instruments.

4. Once approved, the batch is shipped to one of Technicon's distribution centers. A portion of the batch is retained for one year after the product expiration date for further testing should the product exhibit problems in the field. Additionally, if the reagent is a new technology, or a particularly short-lived reagent, such as hematology reagents, portions are held back for periodic testing of potency. If a batch has to be recalled, Technicon notifies all customers through a notification bulletin.

Our manufacturing practices comply with all FDA requirements relating to: quality assurance; facility; equipment maintenance; calibration procedures; written manufacturing specifications and processes; validation program for manufacturing and testing procedures; final product inspection and evaluation; warehouse and distribution control; maintenance of manufacturing records and complaint files; control of components used in manufacturing; packaging and labeling information on: (a) accuracy, precision, sensitivity and limitations of tests performed by the instrument; (b) necessary maintenance and calibration procedures; (c) scientific principles of the test procedure; and (d) scientific references which document the above information.

In other words, every conceivable step is undertaken to ensure that equipment, reagents, and other laboratory supplies meet the highest standards of quality before being placed and utilized in the clinical laboratory.

Placement of Instruments, Training and Servicing

Before a laboratory can purchase Technicon instruments, the lab must agree to have at least one of its laboratorians trained by Technicon prior to instrument placement. Usually, this training program of one to three weeks instruction is conducted at Technicon's Tarrytown facility; instruction programs vary depending upon the machine being placed. Technicon also provides trainees with extensive lab manuals for future reference, including Operation Protocol, Operation Guide, FDA Manual, Product Labeling Manual, and in some instances, a video tape on system operation.

Typically, after training is complete, Technicon ships the instrument to the lab. An extensive installation protocol is followed at the site. A Field Service Engineer and Technical Specialist run the system through a series of tests and verify that the system meets all FDA labeling specifications. Once the testing is complete, a report is compiled and the system is formally signed over to the customer. A Technical Specialist stays on site for three to five days to ensure that the system is operating and that the lab personnel are properly trained.

A Field Service Engineer and a Technical Specialist remain available through a 24 hour telephone service line to respond to problems and for retraining when necessary. Further, contracts provide for guaranteed on-site servicing and instrument warranties.

Technicon currently is developing a program called "In-Field Training" that will employ a Technical Specialist and a technically trained instructor to retrain lab personnel, thereby allowing the Field Specialist Engineer to spend full-time servicing machines. Additionally, Technicon is considering the possibility of utilizing interactive video training whereby technicians can train or refresh their skills through a computerized, interactive training system associated with the laboratory analyzer.

Thus, Technicon has taken extraordinary measures to ensure that equipment and ancillary products are appropriately utilized once Technicon places an instrument in a laboratory. Nonetheless, errors in lab testing do occur.

Source of Lab Inaccuracies

As noted in the testimony submitted to your subcommittee by the Health Industry Manufacturers Association, a recent conference on "Managing the Quality of Laboratory Test Results" identified over one hundred factors that can affect the quality of test results, ranging from improper sample collection to misinterpretation of the results. As a manufacturer of automated diagnostics systems, we have had the opportunity to observe errors which are associated with the use of the automated equipment as well as to develop new technologies which will help eliminate or at least minimize the likelihood that consequential human error will occur.

Several witnesses have presented testimony to the Subcommittee which concluded that the competence of lab personnel contributes significantly to the quality of lab performance. Unfortunately, as the American Society of Clinical Pathologists stated, the quality of non-physician lab personnel is declining. Many factors are contributing to this decline.

For instance, fewer students are pursuing the laboratorian professions, in part as a response to a perceived negative image of the vocation as well as due to fear of exposure to infectious diseases, such as AIDS. Consequently, the pool of available laboratorians is diminishing. Furthermore, there is an extremely high rate of turnover with respect to laboratorians; accordingly, in many cases, lab personnel operating machines have been trained, not by the equipment manufacturer, but by another laboratorian who perhaps lacks adequate competence or training himself and who probably is not versed in lab training skills. Finally, and perhaps most importantly, labs are being driven by reimbursement reductions to reduce costs wherever possible; frequently labs choose to hire less-trained, lower cost personnel to help compensate for reimbursement reductions. Indeed, as the American Society of Medical Technologists noted in its testimony, physicians office laboratories ("POLs") often are utilizing on-site and untrained help, such as receptionists or high school students, to perform lab tests, thereby saving additional personnel costs.

Common mistakes of untrained or incompetent personnel include:

1. The use of outdated reagents; laboratorians may misread reagent labels and consequently use impotent, outdated reagents. Personnel also might pour one reagent into an empty reagent container, making it impossible to know the expiration date of the replacement reagent.

2. The use of the incorrect reagent to analyze a blood specimen by carelessly mixing up reagent vials or by pouring one type of reagent into an empty container labeled for another type of reagent.

3. Failure to regularly calibrate automated machinery or incorrectly calibrating machines resulting in machine malfunction.

4. Accidental interchange of patient specimens so that patients receive results of another patient's analysis.

Manufacturers' Response to Lab Inaccuracy -- Automation Today and Tomorrow

Although 100% technological accuracy is not attainable, Technicon's systems technology, like that of other manufacturers of highly automated equipment, is evolving to minimize the likelihood of human error which will result in inaccurate lab test results. What is our incentive to develop those automated systems? Obviously, ensuring that the consumer is afforded the highest quality lab service is of paramount priority. As several witnesses have indicated in testimony to the Subcommittee, advancing technologies which have led to lab automation have resulted in increased precision and accuracy. Moreover, automated systems reduce the costs to labs in providing services; thus, in an environment in which reimbursement is being ratcheted downward, automated systems enable higher volume labs to increase profit margins. Parenthetically, one should note that these advances in technology have emanated, not from regulatory mandates, but from a competitive marketplace.

Technicon's CHEM-1 machine, which was first marketed in 1987 embodies state-of-the art technology designed to reduce the incidence of human error:

1. The machine is computer-programed to force the technologist to perform daily startup checks and the necessary calibration to ensure proper machine function. If the machine is not calibrated properly, it will not run, requiring the lab personnel to adjust the machine.

2. The reagent containers in the CHEM-1 are designed so that they cannot be refilled and personnel cannot transfer outdated or improper reagents into them. Additionally, the safety-designed containers prevent the laboratorians from personally handling the reagents; instead of the technologist mixing the reagents, the machine itself crushes the reagent tubes within the container to dilute the reagent or to mix the reagent properly. Further, the reagent containers are barcoded with information on the reagent type, lot number, expiration and number of tests per reagent pack. The system will not permit the technologist to run a test if the expiration date has been passed or if the pack does not have enough reagent to run the tests requested.

3. Patient specimen tubes can be barcoded before being placed in the machine to ensure that technologists cannot accidentally interchange specimens.

In the near future, an automated-closed tube sampler option will be added to the H*1, permitting the operator to sample patients' specimens without ever removing the stopper from the blood collection tube. This option will reduce the potential exposure of the laboratorian to infectious agents, like the AIDS virus.

It is likely that during the next decade, the laboratory environment will become even more robotocized in response to the need to reduce the possibilities of error, to increase laboratory safety, and to control costs.

There is, we must acknowledge, a "downside" to laboratory automation. The availability of more highly automated systems enables labs to hire personnel with lesser skills and training, perhaps contributing to the decline of the skilled laboratorian market. The advancing technologies also have made feasible the performance of many tests in the physician office lab ("POL"). The POL poses particular problems for accurate testing because, as noted in testimony presented to the Subcommittee by the American Clinical Laboratory Association, the American

Association of Bioanalysts, the American Society of Medical Technologists, and Dr. Alan Fisher of the Medical College of Georgia, personnel performing tests in POLs tend to be less well trained and less experienced. As several witnesses testified, it is not surprising that there exists a correlation between high quality labs and well-trained personnel. Unfortunately, machines with built-in accuracy mechanisms such as the CHEM-1 described above, range in cost from $125,000 to $350,000 and are typically too expensive to be placed in the lower-volume POL environment. Consequently, machines placed in POLs still tend to rely on the skill of the laboratory personnel to responsibly handle specimens and reagents and to calibrate machines as needed. It is important to understand, however, that even with highly automated machines, personnel need to be well-trained in order to perform testing on as error-free basis as is possible. Accordingly, it remains one of Technicon's priorities to insist upon and offer extensive training prior to the placement of any instrument.

Policy Recommendations

In light of the foregoing information, and the additional concerns which were expressed at the Subcommittee hearings, Technicon offers the following policy recommendations:

1. Need for well-trained personnel. As virtually all of the testimony presented at the hearings noted, in order to achieve the highest possible accuracy in lab testing, it is imperative that the personnel handling patient specimens, operating lab equipment and, in some instances, interpreting results are appropriately trained and experienced. Technicon, like other manufacturers, is dedicated to assisting in the training of lab personnel. However, without appropriate training requirements, and possibly certification or proficiency exam mandates, labs may not take full advantage of the hands-on training which manufacturers offer. We believe that federal and state regulatory mechanisms should ensure that lab personnel be subject to training and certification requirements relevant to the particular services being performed, and it would appear that some personnel requirements should be imposed on personnel utilized by POLs.

2. Need for Proficiency Testing Programs. As the Health Industry Manufacturers Association has noted, proficiency testing programs have been of substantial assistance in helping laboratories improve their testing performance. Technicon supports voluntary -- and, where appropriate, mandatory -- participation of labs in proficiency testing programs.

3. Need for Uniform Federal Standards and a Model State Regulatory Statute. One of the current problems with regulation of clinical labs is the inconsistent and confusing regulatory framework under which these labs operate. Technicon supports the Health Care Financing Administration's current efforts to unify federal standards under Medicare and the Clinical Laboratory Improvement Act of 1967. Additionally, the federal government should adopt a model state regulatory statute to promote consistent regulation of labs throughout the states.

4. Need to Develop Standards in Consultation with the Medical and Clinical Lab Community. It is essential that governmental bodies approach lab regulation thoughtfully. Federal and state regulators should consult with the medical and clinical lab communities as legislation and implementing regulations are developed in order to ensure that requirements are carefully tailored to the various lab settings and to the complexity and type of tests being performed. Additionally, regulations should be sufficiently flexible to accommodate and promote the development of new technologies which have proven to be central in improving lab accuracy while decreasing marginal costs.

5. Need to Impose a Moratorium on Reductions in Lab Reimbursement. It is inarguable that Medicare and third-party reimbursement reductions have forced labs to reduce overhead costs, including adequately trained labor. It is also likely that some labs have sacrificed other quality control measures in order to compensate for reimbursement reductions. Technicon understands that Congress has commissioned the General Accounting Office to study the effects of reimbursement reductions on the quality of lab testing. It is imperative that further alterations to reimbursement policy be suspended until this study is completed.

6. Need to Curtail Fraudulent and Abusive Lab Practices. We share the Subcommittee's concerns regarding reports on reimbursement abuses and referral arrangements between labs and physicians which would appear to subordinate the interests of the patient to the financial enrichment of providers. These practices threaten the public health and safety and undermine public confidence in an industry which has made remarkable strides in improving diagnostics. These who waste scarce fiscal resources and commit fraud and abuse upon the Medicare program should be punished.

Conclusion

Technicon continues to be dedicated to achieving the highest attainable quality for the clinical lab industry and is prepared to work with the Congress to develop a regulatory system that will facilitate this goal.

5995C

STATEMENT OF THE NEW YORK CITY DEPARTMENT OF HEALTH

DIVISION OF LABORATORY IMPROVEMENT

Prepared for Incorporation into the Record of the
Hearings by the Subcommittee on Oversight
of Government Management Committee
on Governmental Affairs
Concerning the Health Care Financing Administration's
Management of Medical Laboratories
held on March 23-24, 1988

Submitted by:

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April 22, 1988

New York City Laboratory Improvement Program

I. History:

New York City has had a comprehensive Laboratory Improvement Program including personnel certification at all levels and laboratory licensure since February 4, 1963. The proficiency test portion was included into the law in 1967. It's existence had been implied in the 1963 version. At that time, it consisted of three specialties. Shortly thereafter Bacteriology and Syphilis Serology were added. At present the New York City program consists of the following: Diagnostic Immunology, Syphilis Serology, Syphilis (Treponemal), Diagnostic Immunohematology, Transfusion Technology, Urinalysis, Pregnancy Testing, Routine Clinical Chemistry, pH Blood Gases, Therapeutic Substance Monitoring, Endocrinology, Drug Analysis (Qualitative), Emergency Toxicology, Blood Lead, Erthrocyte Protoporphyrin, Zinc Protoporphyrin, Hematology, Comprehensive Coagulation; Bacteriology, GC Smears - General, Mycobacteriology Smears, Cultures, Mycology and Parasitology. New York City was among the first to have a proficiency test for Drugs-Subject-to-Abuse (Qualitative) in the country.

In many aspects of its comprehensive Laboratory Improvement Program, New York City was the pioneer and used as the model for regulatory legislation for other states, CLIA'67 and for New York State.

The following are the recommendations for Federal participation and pertinent legislation.

II. Recommendations:

The question that is addressed is: What should the Federalgovernment do to ensure quality output of testing from the nation's clinical laboratories?

It is recommended that the Federal government develop and support a national program that has the following features.

A. Require annual registration of all laboratories that perform clinical testing regardless of their locations. Thus physicians' office laboratories as well as hospital and independent laboratories, HMO's, etc. would be included.

In order that it may be determined where clinical laboratory testing is being done, it is essential to identify the places and define the activities that are performed. Reregistration should be annual in order that changes may be known.

B. Provide for inspections at least annually. It is important that if expansion of the inspection program is undertaken that appropriate funding be allocated. It is possible that some physicians' office laboratories may be exempt. This program could be an extension of the Medicare and/or CLIA regulatory process and its annual inspection or another inspection program which is different from both in that it might allow for different types of inspection depending upon the complexity of the registered laboratory.

C. Mandatory verified participation in a proficiency testing program which employs a nationally defined grading system which is designed to identify poor performance. This service should be accompanied by a system of mandatory curtailment of services for those areas where the designated performance levels are not met. The grading system should consider clinical utility and significance of test results as well as the analytical aspects.

D. Establish appropriate Personnel Standards - It may be that an extension of the Medicare and CLIA standards can be expanded or revised so that they will be applicable to those laboratories at present not included under either. In any case standards should be developed for personnel in the non-Medicare,-non-CLIA and at present, totally unregulated laboratories. It has been demonstrated that the quality of laboratory testing is related to the training and/or educational background of the individual performing the test. Since many physicians have had little or no experience and/or training except, for the presentation made by the representative of the equipment manufacturer, office personnel standards for physicians' office laboratories are needed.

It might be appropriate to mention that non-M.D. doctoral level scientists with appropriate experience should be permitted to direct clinical laboratories. It would also appear that HHS examination is no longer appropriate to qualify laboratory personnel at the technologist level.

E. Require a Quality Control Program - Such a program should be mandated with standards defined by the government. It should include such definitions as types of control material, frequency of use, minimum limits, and policy for review of results and actions required when results exceed these limits. At the time of annual inspection, all aspects of the quality control program should be checked to see that these standards have been met. The program as designed should have a blind specimen submission component of some description. It might be the use of split samples or repeat samples or samples from some external source.

These are the critical areas as seen by New York City. Although its program is far more extensive and provides for stringent requirements, the national standards set forth would apply to laboratories never before regulated. A series of minimum standards should be implemented as soon as possible with a view toward revision in the near future.

For those laboratories which at present perform a variety of more complex tests and are not regulated, it would be appropriate to extend a revised version of the Medicare and/or CLIA'67 standards. The more uniform the standards are, the better the control and implementation would be as far as the entire laboratory community is concerned.

The goal of legislative action is to obtain the best results for all patients so that all may receive equally the highest quality medical care.

New York City Proficiency Test Program

Year	Specialty	Samples x Analytes	Tests/Yr	Challenges Per Year	Results Eval.	Unaccep. (%)
1963	Clinical Chemistry	2 x 22	4	176	450	34 (8%)
1963	Immunohematology	4 x 6	4	96	280	9 (3%)
1963	Blood Services	5 x 12	4	240	340	3 (1%)
1967	Complete Blood Count	2 x 7	3	42	126	10 (8%)
1967	Hem. Comprehensive	3 x 9	3	81	422	27 (6%)
1967	Coagulation	3 x 2	3	18	25	1 (4%)
1967	Syphilis Serology	5 x 2	2	20	554	36 (17%)
1967	Bacteriology	12 x 1	2	24	313	4 (1%)
1971	Diag. Immunology	2 x 7	2	28	442	47 (11%)
1971	Mycology	12 x 1	2	24	73	3 (5%)
1971	Mycobact. (Smears)	5 x 1	2	10	14	0 (0%)
1971	Mycobacteriology	10 x 1	2	20	77	9 (12%)
1972	Drug Abuse	8 x 2	3	48	81	12 (15%)
1975	FEP	6 x 1	4	24	12	2 (17%)
1975	Blood Lead	6 x 1	4	24	24	3 (12%)
1975	Parasitology	5 x 1	2	10	258	18 (7%)
1976	Urinalysis	3 x 5	2	30	455	6 (1%)
1976	G.C. Smears	4 x 1	2	8	51	0 (0%)
1977	Endocrinology	3 x 14	4	168	700	45 (6%)
1977	TDM	3 x 17	4	204	680	38 (6%)
1978	Preg. (Urine)	3 x 1	2	6	384	17 (4%)
1982	pH Blood Gases	3 x 3	4	36	347	16 (5%)
1985	Zinc Protoporphyrin	6 x 1	4	24	96	21 (22%)

Cytology Proficiency Program

I. History

The New York City Department of Health has been conducting a comprehensive Cytology Proficiency Program since 1977. The program consists of:

1. On-site inspection using Medicare Guidelines.
2. Cytology proficiency testing.

This program is based closely on the modus operandi of all cytology laboratories including those without cytotechnologists and assesses individual performance as well as the laboratory as a whole. On-site testing by investigators who are certified cytotechnologists, is a prime requisite.

Materials and Methods

Cervicovaginal (CV) and pulmonary smears are selected by the cytopathologist. All smears either suspicious or positive for malignancy are confirmed by biopsy or autopsy. Negative CV smears and negative sputum smears are obtained from patients who showed no evidence of malignancy. All smears are submitted to reference laboratories for independent interpretation and for determination of adequate staining technique. Final selection of smears for test-sets is in complete agreement of interpretation by at least three reference laboratories.

Test Procedures

A set of 10 test specimens, consisting of 7 CV and 3 pulmonary smears is presented to each cytotechnologist for examination. Pertinent data including the patient's age, if relevant, the last menstrual period, and any other clinical history is submitted with each smear. The cytotechnologist gives the diagnosis for each smear in the appropriate column. The pathologist reviews each smear and initials the results of the test, if he is in agreement with the cytotechnologist or initials his diagnosis. The cytotechnologist and the pathologist are rated independently.

In laboratories employing no cytotechnologists the pathologist does his own screening and makes all interpretations. The laboratory director may take the test himself, or he may assign it to an associate who ordinarily renders interpretations of cytology specimens for the laboratory. .

In a large laboratory, with several cytotechnologists and several pathologists, one pathologist may review the findings of any number of cytotechnologists, or this may be done by several pathologists, or even several pathologists may review and initial the findings of one cytotechnologist. Only one result is acceptable on each slide. The report is signed and dated by the cytotechnologists and pathologists who read and review the slides.

Grading Tests

For the pathologist and the cytotechnologist satisfactory performance was defined as no more than one error on a set. Two errors out of 10 slides is considered failure. In this case a retesting is necessary. A laboratory failing to achieve 90% on the second test is informed by letter to the director. The laboratory is not retested until the pathologist responsible for the routine reporting has participated in a formal educational program of at least five days duration. Documentary evidence of participation in this educational program must be submitted before the third test is scheduled. An unsatisfactory performance permits a laboratory to be retested up to a total of three times in any test year and this process provides a true indication of those laboratories that are in need of further instruction in cytodiagnosis. The attached table indicates the results of proficiency testing in cytology for 1987.

Reporting of Tests

The first step is to correct the completed tests by manual method. Individual critiques are sent to the pathologists which include a report on each cytotechnologist in addition to a report of the general inspection.

II. Recommendations

Based on our experience in New York City, we believe that a National program should have the following elements:

1. Mandatory on-site inspections using uniform guidelines for all Cytology Laboratories (Medicare and/or non-Medicare), conducted by certified cytotechnologists.

2. Mandatory proficiency testing using clinical case material in conventional format (slides).

3. Mandatory quality assurance program requiring:

   a) Documentation of cytotechnologists' and pathologists' diagnostic accuracy rates and/or percent positive findings.

   b) Mandatory ceiling on the number of slides/screener.

   c) Rescreening of 10% of negative cases and/or negatives in high risk groups.

d) Mandatory blind resubmissions.

e) Statements indicating the absence of endocervical components on the report, when appropriate.

f) Submission requirement of name and/or I.D. of patient on the slides.

III. Other Recommendations:

In view of the existence of a nationwide shortage of certified cytotechnologists, the following recommendations are suggested:

1. That the federal government fund allocations to support or create Schools for Cytotechnologists.

2. That the federal government fund allocations for continuing education.

3. That the federal government fund allocations for the development of automated cytology equipment, that would help to alleviate the manpower crisis.

STATISTICS FOR CYTOLOGY PROFICIENCY TESTING (1987)

Total Number of Laboratories Tested	93
Total Number of Pathologists Tested	103
Total Number of Cytotechnologist Tested	174
Total Number of Pathologists - 1st Failure	3
Total Number of Pathologists - 2nd Failure	0
Total Number of Pathologists - 3rd Failure	0
Total Number of Pathologists Retested	3
Total Number of Cytotechnologists - 1st Failure	10
Total Number of Cytotechnologists - 2nd Failure	0
Total Number of Cytotechnologists - 3rd Failure	0
Total Number of Cytotechnologists Retested	10
Total Number of Pathologists Retested After Refresher Course	0
Total Number of Cytotechnologists Retested After Refresher Course	0

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F. Michael Walsh, MD
President

March 28, 1988

The Honorable Carl Levin, Chairman
The Honorable William S. Cohen, Ranking Minority Member
United States Senate
Committee on Governmental Affairs
Subcommittee on Oversight of Government Management
442 Hart Senate Office Building
Washington, DC 20510-6250

RE: Subcommittee's Examination of Accredidation Inspection and Oversight of Clinical Laboratories Under the Clinical Laboratories Improvement Act of 1967. Request for written response to questions posed in the Committee's letter of March 4, 1988.

Dear Senator Levin and Senator Cohen:

Question 1. Assess the current quality of lab testing, including testing performed in physicians' offices and specific conditions or practices that now exist in labs which adversely affect the quality of test results:

The overall assessment of the quality of labs is variable, running the spectrum from excellent to unacceptable. There is no general consensus statement that can be made about "Laboratories". Specific statements, however, do apply to the different categories of laboratories that include university hospitals, medical centers, community hospitals, for profit hospitals, local laboratories ("mom and pop"), regional reference laboratories, large commercial reference laboratories, specialty laboratories; and physician office laboratories. Each one of these categories will vary within the group as to the level of technical competence, expertise and the quality of testing provided. In general, however, testing provided by institutions is generally of a higher caliber than that provided by small "mom and pop" laboratories. Large commercial chains are variable, but generally provide good overall quality. The category of phyisicans' office laboratories is distinctly different and present an extremely high level of variability as to the quality of tests. Generally, simple procedures can and, in many instances, should be performed by physicians' offices. This "simple test" category includes hemoglobins, urinalysis and dip-stick type methods for glucose, etc. Methods which are technically complicated should not be done in the office environment due to the lack of adequate training of the staff, low volume and inherent high per unit cost.

Laboratories are under significant cost pressures, many of which have been self-imposed to maintain stated levels of profitability. In my opinion, there are too many laboratories competing for a contracting financial base in the market place. In addition, particularly in the Northeast, the availability of technologists and technicians is extremely tight and, therefore, individuals of marginal to unacceptable quality are hired because of the manpower shortages. Testing by many laboratories, however, has expanded in many instances beyond the laboratory's capabilities. In part, this is due to a perceived market pressure to be "full service"; i.e., offer a complete testing menu. In addition, the ready availability of equipment and diagnostic technology that fail to perform in a consistent and reproduceable fashion unless supervised by highly competent personnel increases the probability of unacceptable results. Many assays have highly variable or poorly reproduceable performance characteristics and "transparency" between laboratories cannot be readily achieved due to the lack of methodologic standardization.

Consolidation of the laboratory industry is the most appropriate way in which to achieve a higher level of quality. Hospitals need to clearly evaluate the use of core laboratory facilities and the formation of networks for the performance of other than STAT testing. There is no rational explanation other than the institution's ego for the duplication of expensive instrumentation and technology. Physicians' offices should be allowed to do testing only which is necessary for the immediate evaluation of specific patients, i.e., a hematologist/oncologist should be able to do hemoglobins, white counts and platelet counts; pediatrician hemoglobins and beta strep cultures, etc. There is, in my mind, no justification for broad testing capabilities in physicians' office laboratories since they cannot be warranted, and it is primarily from a perceived economic incentive to the physicians that the services are made available.

Question 2. The role of personnel qualifications, quality control standards, proficiency testing and inspection programs in ensuring quality lab testing.

These programs have a strong impact in improving and maintaining the consistency of laboratory testing. With the expansion of the technical requirements of the laboratory, specific qualifications for the personnel are mandatory. Each discipline within laboratory medicine has established requirements for competence and requires individuals who are both theoretically trained as well as practically experienced. As an example, New York City and New York State have well defined personnel qualification programs which are designed to insure that those individuals who function as directors, supervisors, technologists and technicians have adequate training and experience in the specific areas of licensure to warrant a specific category designation. The lack of standardization of personnel qualifications leads to individuals who are poorly or inappropriately trained performing tests that they are not adequately trained to do, thus yielding a higher level of unacceptable values.

Quality control standards are mandatory. Many of them are set to assure that a specific format is followed in the performance of tests. The overall quality assurance programs are designed to look at "the production engineering" format of a clinical laboratory. Again, the basic thrust is to be able to document that the assay is in performance specifications prior to the release of patient results. Unfortunately, many laboratories in the name of cost-containment bypass adequate quality control and quality assurance programs. This has a much higher probability of being corrected if there is consolidation of the laboratory, since it would be easier to police and oversee the adherence to said programs.

Proficiency testing is also mandatory. In New York State, unannounced inspections where the Evaluator watches the analyst perform the tests are conducted. In my judgement, this is necessary. I have seen too many instances of less than ethical activity in laboratories where the proficiency samples are performed by an outside source or the most experienced technologist, and thus does not adequately evaluate the actual performance of the laboratory. Unfortunately, this does not occur in the regular course of business. Performance on proficiency studies must be compared against an accepted standard or reference laboratory to indicate whether the participating laboratory is consistently achieving acceptable results.

Inspection programs, particularly unannounced, have a very positive effect on the laboratory. There have been too many instances in which a laboratory fails to consistently follow the standards and only respond and comply in the period prior to a scheduled visit by an accrediting agency. A consultative approach by the Inspector where he or she aides the laboratory in improving its operation is of considerably greater value than the punative approach used by some agencies.

Question 3. Assessment of the role performed by private, voluntary accrediting organizations in ensuring quality testing.

The College of American Pathologists and the Association of Bioanalysts have well designed programs. The College has focused on this area for years and has refined it on a continual basis. I believe the programs to be fair and adequate in the evaluation and designed to continually advance the requirements and standards so as to be able to judge the performance specifications of the laboratory on an on-going basis including new technology.

Question 4. The appropriate role of the Federal Government on ensuring quality and accountability on lab testing performed in physicians' offices:

This is going to require a two-pronged approach. One is to control the rapid development of instrumentation and diagnostic products by the diagnostic companies that are designed, in many cases, in haste and have not been clearly evaluated as to their reliability and reproduceability. From the physicians' office standpoint, doctors either do testing for convenience or a perceived economic benefit. As previously stated, if a physician is trained in a specific discipline, such as hematology, etc., there are reasons where tests which are appropriate for that physician's level of training and patient population should be allowed to be performed within the office. However, laboratory testing under no circumstances should be performed in the office.

In my judgement, the best way to curtail office testing is to enforce the personnel qualification standards. Since the technical market has shrunk significantly over the past few years, it will be exceptionally difficult for a physician's office laboratory to be able to hire, train and maintain qualified individuals for the performance of a low volume of testing. In addition, the mandatory subscription to a proficiency study must be required. This will be able to delineate whether or not the laboratory is performing within certain guidelines. Inspection and accreditation programs also can determine whether or not the laboratory has effectively organized itself and is appropriately managed.

It must be underscored that proficiencies and inspection and accreditation programs can only give a static view of the laboratory at the time it was evaluated. From an on-going standpoint, many laboratories show an exceptionally high degree of variability and inconsistent adherence to standards set forth by accrediting agencies. In addition, one of the primary objectives of any clinical laboratory is service which is defined as the appropriate performance of tests within defined time frames that are consistent with good patient care and management. A laboratory might have high personnel standards, such as a research laboratory; however, it may disregard the clinical requirements of patient management and thus yield a significant delay in testing. On the other hand, the quick testing performed in the physicians' office market might be done for patient convenience but by individuals who are incapable of bringing quality results due to lack of training and/or supervision.

5. Recommendations for Federal action.

I believe the precedents set forth by New York State and the College of American Pathologists are well designed and should be used as models for the Federal Government. Programs which have been instituted by HCFA in regards to reimbursement create the economic incentive for laboratories to

Differential
Diagnostics Inc.

start considering consolidation, formation of core network laboratories and press the smaller laboratories to assess their positions. Unfortunately, many of the laboratories have resulted to significant operational cost cutting techniques to maintain profitability that have adversely affected quality. The Federal Government should clearly attempt to forge a global policy that would not only increase the level of standards as they apply to personnel, laboratory management and structure and proficiency, but also reward those hospitals and/or commercial laboratories that make wise business decisions to consolidate and achieve the necessary level of expertise and cost-effectiveness to justify their existence.

I do not subscribe, nor believe, that physicians' offices should indiscriminately do testing. I feel that the arguments of patient care and convenience are highly outweighed by the lack of adequate supervision, defined performance levels and consistency of quality. Unfortunately, the majority of physicians who perform laboratory testing do it for economic benefits rather than patient care.

In summary, the laboratories in the United States are in an era of significant cost containments coupled with contracting the technical labor pool. Most of the methods available in the routine clinical laboratory are well defined, and if performed in the appropriate environment, will yield quality results. The creation of factories for the production of test results has a place for tests which can be put on a production line format, such as general chemistry and/or general hematology. Specialty testing, such as cytogenetics and immunology, must be handled in a different format and cannot be placed in a production environment. The performance of tests at random sites by unqualified individuals will obviously yield inadequate results. Therefore, in my judgement, the Government should use standards that have been clearly defined by New York State or the College of American Pathologists as general guidelines for the overall operation of the clinical laboratories.

Respectfully submitted,

F. Michael Walsh, M.D., MBA,
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March 29, 1988

United States Senate
Committee on Governmental Affairs
Subcommittee on Oversight of Government
Management
442 Hart Senate Office Building
Washington, DC 20510-6250

Senator Carl Levin, Chairman
Senator William S. Cohen, Ranking Minority Member

Gentlemen:

I am pleased to have an opportunity to provide written testimony for the Subcommittee on Oversight of Government Management hearings on the federal government's role in ensuring the quality of medical laboratory testing.

As a California licensed and nationally certified clinical laboratory scientist for the past thirty-three years, I have worked at the bench as a hospital laboratory manager. I am now a self-employed laboratory management consultant and serve as Laboratory Operations Advisor for the Chicago office of Ernst and Whinney. I am also adjunct professor at the Center for Advanced Medical Technology's graduate program in Clinical Sciences at San Francisco State University. I teach five different laboratory management courses.

My professional activities have included three years as a member of the American Society for Medical Technology's Board of Directors and three years as a Presidential officer.

These activities plus my work experience have resulted in many invitations to present seminars and workshops on all aspects of laboratory operations and management. And my consulting work has taken me to many laboratories across the country. A full summary of professional experience is appended.

These comments reflect my experience and observations of laboratories across the country as well as input received from hundreds of technologists and doctoral scientists who attend my educational programs. The remarks will focus on laboratory operational and delivery systems that influence quality and the validity of today's quality assurance programs. I hope they will be of help to the committee in its deliberations.

FOCUS

The quality of laboratory test results is influenced by many factors. These include:

- The knowledge and skill levels necessary for performing the test;
- Accurate and reliable equipment and reagents;
- Appropriate process (quality control) and outcome (interpretation and correlation) validations;
- Diagnostic and therapeautic application of test results and
- Effective management and organization of the laboratory.

I have been told of or personally observed deficiencies in all of the above area.

PHYSICIAN OFFICE LABORATORIES

It is not unusual for small doctor's office laboratories to assign laboratory testing to individuals who have no knowledge or experience in clinical laboratory sciences. They are not experienced in the proper use and care of instruments and seldom perform quality control. Reagents are often outdated and test procedures obsolete.

The responsibility for assuring quality results rests with the physician owner(s). And, since few physicians have sufficient understanding or knowledge of laboratory techniques, they are often unable to differentiate correct from incorrect results. As a hospital laboratory manager I was often faced with trying to explain to a physician why the results of tests he performed in his office were different from those we did. Most of the time the physician felt we were in error. If we couldn't convince them otherwise, the patient was the loser.

Today the problem is compounded by the plethora of instrument manufacturers who purport to sell instruments that need little or no attention. Their instruments range from excellent to mediocre. But they all require monitoring, maintenance, quality control and some knowledge of their operating principles.

Some states require physician office laboratories to participate in proficiency testing programs. I know of hospital or reference laboratories that have run the physician office proficiency test samples because the physicians were their clients for other tests and they didn't want them to take their business elsewhere. The physicians then reported the results as though they had performed them.

In my experience I have found quality testing in physician office laboratories where there were licensed or certified technologists or technicians performing the tests and having responsibility for the testing process.

ALTERNATIVE DELIVERY SYSTEMS

Another area of concern for laboratory testing is that performed on hospital wards and in alternative delivery systems or providers, such as ambulatory care clinics. When the hospital laboratory supervises and has responsibility for testing done by nurses or other non-laboratorians the results are more likely to be of acceptable quality. And when other delivery systems use qualified laboratorians, they are more likely to have proper techniques and systems to assure quality.

While on a consultation I visited a clinic for indigent refugees. I found a clinic employee performing a finger puncture for a test to determine the concentration of red blood cells in such a way that the sample would be totally inappropriate when tested. When questioned the staff told me that they were exempt from existing laws and could not afford to pay for qualified personnel. This situation exists across the country in similar alternative systems.

PROFICIENCY TESTING

Today there is no satisfactory method for assuring quality in laboratory services. Present proficiency testing systems are a start but they tend to confirm good laboratory practice rather than identify laboratories that have poor quality. Not only have I observed personally, but many laboratorians have related experiences in their laboratories as to how proficiency samples are handled when they arrive. It is not at all uncommon for the specimens to receive very special attention. The most experienced staff do the testing and the tests are repeated until there is virtually no sample left. This approach does not truly evaluate the day-to-day performance experienced by the patients.

ACCREDITATION PROGRAMS

Inspection and accreditation programs are one approach to assuring quality of test results. Their effectiveness, however, is directly related to the relevance of their standards and the quality of the inspectors. When the inspection process depends upon paid employees (i.e., JCAHO, Medicare, State Agencies) control and direction by the accrediting agency is more likely.

When volunteers are used, the inspection process is often uneven, as it is difficult to find inspectors who are not professional colleagues of those to be inspected. The intent is objectivity, but the result is often less than that. Of all the criticisms I have heard about inspections this prevails.

The relevance of the accreditation standards is another major factor that impacts on laboratory operations and quality. The technical process criteria that directly relate to the performance of tests and reporting of results are not all reflective of the changes in technology and methodology. They often add unnecessary work and cost and do not always relate to patient outcomes. Quality control standards, for example, do not reflect the built in systems of new instrumentation. The requirements assume that quantity of quality control testing equates with quality. There is not sufficient flexibility to quickly react to changes in the state-of-the-art of laboratory practice.

The accreditation standards for all levels of laboratory personnel are not only inconsistent but inappropriate in many instances. They were instituted many years ago and fail to recognize the changes in required levels of knowledge and skills as well as operational needs. This is particularly true at the director level.

To assume that one individual can have the necessary qualifications to be responsible for the administrative, technical and medical components of laboratory operations is to ignore reality. There are three distinct areas and each one requires special expertise. The traditional belief that a medical or doctoral degree automatically conveys the ability to manage all three areas is erroneous. Few, if any, medical school programs prepare an individual for administrative functions and focus only briefly on the technical areas of the laboratory.

Doctoral programs focus on a specific specialty area and do not have management courses either. If the doctoral person does not have a generalists technical background, it is difficult to appreciate the problems in all areas of the laboratory. The same problems exist when technologists lack management skills and generalists experience.

I have observed many laboratories where the final decision rests with those who do not have the knowledge to make those decisions. And, if they are personally insecure in their positions, these decisions could be harmful to patients. I have seen a specialist laboratory director tell a blood bank technologist to change the expiration date on units of blood for transfusion even though they were outdated. I have seen a medical director tell technologists to run clotted spinal fluid cell counts even though the results would be of no value to the patient and will add significant costs. So the degree credential of a director does not guarantee appropriate knowledge and skills.

The body of knowledge and skills required to perform today's comprehensive battery of clinical laboratory procedures is extensive. As a matter of fact, **the usual clinical laboratory sciences undergraduate curriculum is more comprehensive then that of a pre-med student.** Where qualified technical personnel are employed to do the testing quality is more likely to be high. For they can accommodate for deficiencies at the directoral level. But **credentials that reflect only entry level knowledge and skills do not assure competence. If personnel do not upgrade through continued competency programs, their skills will soon deteriorate.** The field has expanded so much in the last ten plus years that it is impossible to function competently without further learning.

RECOMMENDATIONS

Federal action is need to standardize the delivery of laboratory services and to assure the public reliable and high quality results at a reasonable cost. The voluntary effort has been effective but it is too fragmented and inconsistent. Existing federal regulations have also suffered from fragmentation, inflexibility and obsolescence. And they are not inclusive of all testing areas since they do not apply to thousands of physician office laboratories.

State laboratory laws and regulations are minimal and those that have laws have few, if any, regulations for physician office laboratories. None of the governmental or voluntary agencies recognize the three distinct areas of laboratory operations.

To address these issues I would recommend the following:

1. That regulations for all laboratories be standardized so patients can expect and receive quality regardless of where their specimens are tested.

2. That the traditional single definition of a laboratory director be revised to recognize today's expanded laboratory roles and responsibilities in three distinct areas- administrative, technical and medical.

3. That individuals wishing to qualify for administrative and/or technical responsibilities be required to demonstrate successful completion of a certification of licensure examination in one or

both areas. Such examinations are available through existing credentialing agencies. This would apply to medical, doctoral or non-doctoral personnel.

4. That quality control standards be up-dated to reflect state-of-the-art testing equipment, methodologies and computerization.

5. That minimum entry-level standards be established for laboratory bench and supervisory personnel and that a recognized national credential be a bench-mark for entry level skills.

6. That some regulation be applied to physician office laboratories based on complexity of test methodology. And that personnel working in physician office laboratories be required to demonstrate their competency to perform the required tests by successfully passing an existing certification examination. Or, where testing is minimal in volume and mix, that a modified version of the technician examinations be developed. Requirements for personnel and quality control should be adjusted to reflect complexity of test methodology.

7. That the present **proficiency testing program should be revised to assure that the specimens are treated no differently than a patient sample. And, when deficiencies are noted, prompt on-site inspection should follow.**

The ideal proficiency program is, of course, blind on-site delivery of samples. But this is very costly. A way to reduce costs would be to contract out that activity to a laboratory professional organization, such as the American Society for Medical Technology, who could provide the service at a much lower cost than the federal or state government agencies. And, since their members are not likely to have "owner" responsibilities, there is less chance for subjectivity. It is necessary to provide some reimbursement to ensure accountability and reduce conflict of interest.

I would, therefore, suggest that the present governmental and voluntary accreditation agencies revise their inspection process to assure objectivity and lack of bias. And, when considering deemed status, the standards of the voluntary agency requesting that status should not impose unnecessary, unrealistic or costly requirements on the laboratory owners.

8. The **definition of the practice of medicine (in Medicare Law) should be evaluated and clarified so that physicians who know little or nothing about testing procedures are not automatically allowed to do tests simply because they are doing them for their own patients.**

I hope these observations and suggestions will be seriously considered by the committee. I again wish to express my considered by the committee. I again wish to express my appreciation for the opportunity to present this information.

Sincerely,

Annamarie Barros

(Mrs.) Annamarie Barros, MA, CLS (NCA), CLDir (NCA)
Director - Health Management Analysis
Adjunct Professor - San Francisco State University
Laboratory Operations Advisor - Ernst & Whinney

March 21, 1988

Honorable Carl Levin,
Chairman
Honorable William S. Cohen,
Ranking Minority Member
Subcommittee on Oversight of
Government Management,
Government Affairs,
442 Hart Senate Office Building
Washington, D.C.

Dear Senators:

As individually concerned technologists, we appreciate the opportunity to present our views and recommendations to the subcommitte on the issues of medical testing in physicians' offices and clincal laboratory regulations under CLIA 1967.

Sincerely,

Christina Spencer MT(ASCP)H
Christina Spencer, MT(ASCP)H

Mary C. Gross MT(ASCP)H
Mary C. Gross, MA, MT(ASCP)H

Enclosure

RECOMMENDATIONS
TO THE
SENATE SUBCOMMITTEE
ON
OVERSIGHT OF GOVERNMENT MANAGEMENT
ON
REGULATIONS OF MEDICAL TESTING
IN PHYSICIANS' OFFICES
AND
CLINICAL LABORATORIES

The following outlines our views and recommendations pertaining to issues of medical testing in physicians' offices and clinical laboratories under CLIA 1967:

1) Various conditions warrant the performance of laboratory testing in physician offices. Not only as a benefit to the patient in respect to convenience but as a time and cost effective measure for the physician. The patient can receive treatment or medication immediately without telephone calls that can be confusing to the elderly. Results on tests such as urinalysis or prothrombin times can change considerably in the time it takes the specimen to be sent to a reference laboratory--thus giving erroneous results.

Collection, handling and processing of the specimen are of upmost importance whether the test is to be done in the physician's office or sent to a reference laboratory. This applies to the Pap smears, timed glucose tolerance test, and anemia or leukemia test. **No amount of sophisticated instruments, quality control or proficiency testing will replace the inadequately taken specimen or carelessly labeled tube.**

Several situations, related by participants in training workshops for physician office personnel in the past year provide examples of tests being performed by untrained or inexperienced persons. Examples are as follows:

a) A hematocrit of 25% - equivalent to 8 gm% - was done in a physician's office. The patient was referred to a hospital for a transfusion. The hospital repeated the hemoglobin to find it was a normal 12 grams.

b) Blood glucose and cholesterol values vary according to type of method. One office lab reported a glucose to the doctor and sent the specimen to an outside lab for additional testing. The glucose was repeated as part of a profile of tests and found to be considerably different from the office result. The office physician, not realizing that some glucose instruments can vary +/- 50 mg% in the 250-300 mg% range, was sure the mistake was with the outside lab. The instrument representatives indicate that such a variance is not significant as the patient would be in an abnormal range and the physiciann would treat accordingly. A variance this great (+/- 50 mg%) in the normal range could result in the patient being diagnosed as a prediabetic--thus requiring additional, unnecessary and costly testing.

c) **Westegren sedimentation rates were being perform without proper dilution leading to false high values.**

d) **Blood smear differentials** not alcohol prefixed to reduce artifacts before staining with Wright's stain could cause red cell morphology to be, **(1) falsely interpreted** as **abnormal or (2) mask significant diseased cells to go unnoticed,**

e) Urine chemistry dipsticks when misread and the abnormals not being confirmed, can lead insurance companies to deny coverage.

In the case of (a) falsely low hematocrit and (b) abnormal glucose, **proficiency testing** would help alert the physician to inaccurate results, **providing the tech didn't call a friend in another lab for results or send the specimen to an outside lab.** Internal quality control is another way to monitor results either daily, weekly, or monthly. **Many do not understand how to handle the data generated by controls.** They perform a control, check the result against the package insert and assume it is correct. **They are unaware of the wide variance of these ranges and of the corrective measures to be taken when control results fall outside the ranges.** The situations described in (c) and (d) can not be improved or monitored by proficiency testing alone. There is no control available for sedimentation rates. In hematology, knowledge and correlation of interrelated data, standardized and reproducible technique, and experience will contribute heavily to accurate results.

A patient should receive quality lab results from the physician office as well as a licensed medicare or CLIA lab. Some screening tests do not lend themselves to finite values and for some there are no control materials. Because of this the person performing laboratory testing should show evidence of attending a medicare recognized program. **The knowledge of proper collection and handling of the patient's specimen and accurate performance of the test should be a requirement for reimbersment by medicare and/or insurance companies.**

Confirmatory and/or diagnostic tests performed in large volume offices should then be performed by a certified technician/technologist with consultation from a supervisory technologist. **Regulations should require high volume and diagnostic labs employing many technologists to have a supervisory technologist. All laboratory per**sonnel must have knowledge of correct specimen collection and handling. Personnel performing lab tests must: 1) follow a written and approved procedure, 2) test the procedure by use of control specimens and 3) perform preventive maintenance on instruments. The larger labs should be enrolled in an external monitoring proficiency testing program.

2) The current federal regulatory system of clinical laboratories has been too lax with the large labs owned by drug and instrument companies. Here the emphasis is on volume. In order to facilitate the large instruments to be cost effective, highly paid marketing personnel encourage physicians to order group profiles of tests which may not be needed by the patient. Individual or special tests are therefore more costly unless the monthly volume of tests can reduce the cost. **As a cost containment measure less qualified personnel are employed to "man" the machines.**

Abnormal results receive little attention as it is considered the ordering physician's responsibility to evaluate and reorder a test if results are questioned. Consequently the erroneous results may go undetected on specimens that should have been rejected due to hemolysis or specimen deteriation. Rejection rate or notification of an unsuitable sample is rare for fear the physician's account may be lost. It is unpleasant to have a patient return for the collection another specimen. The abnormal results should have been given to a supervisory technologist and then to a medical director. An audit system under control of HCFA/CDC of professionals could spot misuse of large volume testing and review the physician/reference lab business practices. It would also detect fraud and abuse of medical personnel records as recently identified by the New York State Attorney General in medicade reimbersurement of homecare personnel.

3) No one aspect of regulation will ensure reliable laboratory results but a combination of all is necessary. **The quality of personnel is the most important in supplying correct results** for the doctor. The knowledgeable, well trained technologist understands the reason for the test, the procedure, the quality control and most important--sources of error in instruments, reagents or specimens. Simplified instruments often give the inexperienced operator a false security with trust being placed in the instrument, therefore it is not frequently checked. A mentioned in #2, large labs cut corners by using on-the- job trained people who will work nights or weekend hours.

Quality control and the procedure manuals are important as legal documents. **Quality control cost effectiveness is another area where labs will try to cut corners.** Many use wider acceptable ranges of 3 standard deviations (SD) where only three values in one thousand will be out of range with certain exceptions. The rules for these exceptions vary only to allow for wider inconsistencies. Most hospital and pathology directed labs use +/- 2 SD, which alerts technical personnel to subtly developing problems with reagents or instruments. The trained technical person then evaluates the problem, takes corrective action and usually repeats the test.

Proficiency Testing as an outside measuring tool is important, but as previously mentioned these results can be "fudged" - checked out through a friend, sent to an outside laboratory or just repeated several times by the office worker with an average taken before the result is trusted. **Such efforts to guarantee an accurate result would rarely by done on a "real" patient specimen.** The inexperienced, poorly trained person is often threatened by proficiency testing. The trained technician would be more likely to treat the PT sample test as a routine patient sample (performing the test once) and would regard the proficiency test as a measure of his/her performance. If the results are abnormal, it provides a valuable educational experience for the technologist.

Inspections are always dreaded but most of the time they are a pleasant experience. If a conscientious lab has overlooked a problem, they usually want to correct it. An example here would be the repeating of a specimen which follows a specimen with high results to check for "carry over" (to the next unrelated specimen). This can occur on some automated instruments. Most labs look on the inspector as a guest whose experience one respects and whose evaluation one finds helpful and necessary to insure professional performance.

4) **Personnel requirements are most important. The assumption that anyone can do lab tests must stop.** We have a shortage of qualified personnel now which may cause many laboraotories to train on-the-job persons in the future.. We must encourage good students to go into accredited programs instead of schools producing "lab techs". Although quality control, proficiency testing and qualified personnel are additional costs to performing any test, these quality stanards must apply to the physician's office to provide reliable test results. If a physician does not wish to incur these costs, then the tests, should be sent out. Care should be taken as to the commercial laboratory used. Commercial labs - reference labs need tighter inspections, particularly in number of tests required to be done/hour and the quality of their technical people. The marketing aspects of the lab should not over shadow the quality of the test results.

Laboratories not covered by Medicare or CLIA regulations would fall into three categories: a) those doing screening tests only; b) those doing screening plus routine diagnostic tests and c) those doing both diagnostic and confirmatory testing. Personnel for categorie one would receive a certificate through the state after attending an approved program in specimen collection, handling, general QC and procedure manuals. The next two categories would have a technician and/or technologist with consultation from a supervisory technologist. The third category would need to have a supervisory technologist as one of the technologists if there were more than three technologists employed. **These personnel would also need to demonstrate a proficiency in QC, instrumentation and trouble shooting. To qualify personnel for these categories either contracts with the state could be made with schools of medical technology or with state approved educational workshops.** Physician office workshops could provide continuing education materials and help assure the technical personnel to be in compliance with the regulations.

A committee of laboratory professionals familiar with CLIA, Medicare regulations, and physician office practices could assist HCFA with drawing up regulations to replace or amend the present law to be applied to high volume labs doing 5,000 test by 1990. They could also set standards of an audit process to asses ordering practices for reimbursement by HCFA.

In summary, a payment of $10 in a physician's lab for a simple test performed accurately and expeditiously is better use of Medicare's money than one sent to an outside laboratory with results returning two days late. Because the sample deteriated, a normal result could be reported by an on-the-job trained person. If the patient was later hospitalized for lack of treatment, the resulting cost and possible malpractice suit could have been avoided. **Errors in physician offices may not be life threatening, but they can lead to unwarranted expense if not properly performed.**

Submitted by:

Christine Spencer MT(ASCP)H
Christina Spencer, MT(ASCP)H
Workshop Director-Instructor

Mary C. Gross MT(ASCP)H
Mary C. Gross, MA,MT(ASCP)H
Education Coordinator-Instructor

March 18, 1983

Senator William S. Cohen, Maine
and
Carl Levin, Michigan
United States Senate
Washington, D. C. 205 10-6250

Dear Sirs:

I am presently in charge of the operations of two independent laboratories and two hospital laboratoaries performing several million laboratory tests per year. All of my suggestions and opinions contained within this letter are my own and do not necessarily represent the opinions of the Baptist Memorial Health Care System.

With the institution of Standard 1 by the CAP in their inspection process, I strongly feel that they as a volunteer agency have departed from the mission of quality assurance. **My experience has been that the inspection teams now emphasize administrative structure and organizational charts in lieu of inspections of quality control system's methods.** The CAP has placed their emphasis on:

- Administrative responsibility and organizational charts

- Ordering of supplies

- Hiring and Firing

- Purchasing of Equipment

The negative aspects of this system and of voluntary programs in general are:

1. **Conflicts of interest** develop when one group of professionals have authority over all other groups examples of this are:
    - The CAP has become very difficult in their inspection of any facilities which I manage since I became a strong competitor of a member of their board of governors.

    - The CAP could make it difficult for physicians other than pathologists to operate laboratories in competition with them such as Internal Medicine groups or HMO's.

- The CAP has successfully managed to use their inspection and acreditation leverage to effect a change in organization charts subjecting myself and other laboratory managers in this city to pathologists.

2. **Favoritism** - It is human nature to go easy on your own collegues. Volunteer inspectors cannot be held accountable for not reporting deficeincies.

3. **Restraint of Trade** - the CAP can and does use the inspection and acreditation process to market against, harass, and impede their competitors.

4. Monopolies develop in Proficiency surveys and laboratories thus increasing cost as competition dwindles.

5. **Inspectors are untrained, inconsistant unknowledgeable and often disinterested in enforcement of the regulations.**

6. Redundancies develop as competing factions produce their own voluntary systems.

Solutions

1. Emphasis placed on proficiency surveys (blind and otherwise), Personal Qualification for line technologist, technicians, quality control documentation.

2. De emphasis on inspections, especially involving maintenance, safety, environment. Emphasize inspections involving quality control records, procedures, technicians and technologist qualifications, labeling and specimen identification, specimen viability, results reporting.

    - Do not require on site inspection for every small laboratory (less than a certain number of tests per day) Could do 5-10%.

    - Exempt certain semi quantitative and qualitative tests such as urine dip sticks, glucometers, and hematocrits from regulation.

    - Emphasize utilization reduction as opposed to price reduction as a means of saving medicare dollars. The money saved on not running 10 useless tests on a 24 test pannel could be better spent on quality control of the 14 tests that are needed.

- Regulate voluntary inspection agencies such as CAP and JACH to protect users and competitors from the problems mentioned above.
- Do not grant deemed status to voluntary agencies.
- Establish a fee schedule that pays enough to maintain quality and use this fee schedule for every provider of services.
- Pass reimbursement regulations that eliminate incentives for physicians to order unneeded laboratory work.

Sincerely,

Michael V Stevens

Michael V. Stevens, Ph.D.
Director of Laboratory Operations
Baptist Memorial Health Care Systems

viewpoints

An open forum for ideas and opinion on health care and the laboratory

Pathologists Are Not Always Best Lab Directors

By Michael V. Stevens

THE COLLEGE of American Pathologists' (CAP) recently promulgated laboratory directorship standard, the so-called Standard I, is of great concern to me for several reasons.

First, this standard makes it virtually impossible for a non-physician, doctoral scientist to be a director of a CAP-approved laboratory. This directorship issue centers on the question, "Is the operation of a clinical laboratory the practice of medicine?" Certainly some aspects of the clinical laboratory are medical practice, such as anatomic pathology, physician consultations, and interpretation of laboratory panels in light of patient histories.

However, some aspects of laboratory medicine are not medical practice. In fact, the Health Care Financing Administration has defined most clinical laboratory services as non-physician (Part A) services, so it is logical to assume that non-physicians may, and in many cases, should, direct laboratory services.

Although some pathologists may be qualified by training and experience to direct a clinical laboratory, in certain cases other health-care professionals may be better qualified. The choice of a laboratory director should lie in the hands of hospital administrators and the medical staff because they are ultimately responsible for patient care. No other ancillary services in the health-care environment abide by rules like those proposed by CAP. How many hospitals have a physician as director of pharmacy?

A second area of concern is the standard's statement that pathologists must assume "full responsibility for operations and administration." This creates a problem for the clinical laboratory manager and hospital administrator because it means that the purse strings, personnel policies, instrument acquisitions, and ordering of toilet paper will rest solely in the hands of a pathologist who may or may not have any training or ability in management, interest in the financial health of the hospital or laboratory, or knowledge of analytical methods. The pathologist may not even be employed by the hospital or lab or be present at its facility for more than one day per month.

I am director of operations for one of the first laboratories to be subjected to the full impact of the directorship standard. Our laboratory had a change in medical directorship in June of 1987 about the same time the new standard came out. Suddenly, my laboratory, which only four months earlier had been declared of excellent quality by a CAP inspection team, became unqualified. An organizational structure that had worked for several years to produce high-quality laboratory services at a reasonable cost was deemed unfit.

On the one hand, CAP representatives were claiming nationally that the standard was instituted only to ensure that medical directors take their share of responsibility over the laboratory. But at the same time CAP's southeast regional commissioner was demanding that our laboratory change its organizational chart as a prerequisite to accreditation, essentially asking my employer to demote me. I wrote the commissioner requesting specifics on how he wanted the organizational chart corrected, but he never replied. The commissioner's refusal to communicate with me directly was pointed. Inspectors of one of our satellite hospitals chose to discuss the directorship standard only in whispers behind closed doors. Our laboratory has not received accreditation at this time.

I firmly believe interaction, consultation, planning, and reviewing of laboratory operations and quality control with pathologists improves and ensures the quality of a laboratory. But I also know several doctors, lawyers, chief technologists, MBAs, and accountants who share in the administrative responsibilities of various laboratories. These people contribute to the management of high-quality laboratories in positions above, below, and parallel to pathologists. I do not believe that subjugating these individuals to a pathologist will improve the quality of their laboratories.

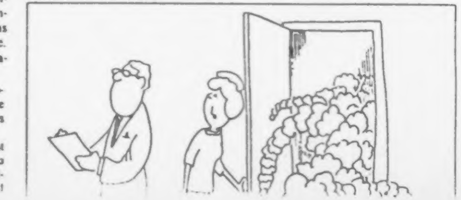
So why has CAP changed its focus from quality assurance to words like control and to organizational charts? In my opinion, it is not for quality assurance—it is for power and money. The new standard will be used to pressure administrators to change organizational charts, placing pathologists fully in charge of all aspects of laboratory management.

Our laboratory competes with a hospital laboratory owned and operated by one of the contributing authors of Standard I. We produce a high-quality product and are bigger, faster, and more economical. Perhaps it is only coincidence that the standard was applied so tenaciously in this instance. But it reminds me of the old story about the rich kid who won't let you play with his ball unless you let him win.

Pathologists have allowed the organization that represents them to be swayed by a small clique of politically oriented autocrats who have been diverted from the prime objective—quality laboratory services for physicians and patients. I hope that all laboratorians—pathologists and non-pathologists—will practice teamwork and cooperation to maintain the goal of quality service at a reasonable cost. If each faction continues to practice self-serving activities to gain some advantage over the other, this objective will become increasingly difficult to accomplish.

The laboratory already has a poor image with the general public. Infighting will only pull public opinion lower. Laboratorians cannot be content to settle important issues like this with internal rhetoric or grumblings, but need to present their case to the American public. So if you want to do something about it write your senator or call the legislative liaisons of your professional societies.

Michael V. Stevens, PhD, is director of lab operations at Baptist Regional Laboratories in Memphis, Tenn.



letters

False Advertising

To the editor: I would like to call attention to an advertisement that Johnson and John-

Belsey *et al.* demonstrated that trained laboratory personnel produce more precise results than untrained health-care workers using a tabletop chemistry analyzer.

I called the number in the advertisement (1-800-527-5577) and told the person who answered I thought the statement in the advertisement was irresponsible and asked

Janice N. Meyer,CLS(NCA)
541 Sandalwood Dr.
Bay Village, Ohio 44140
216-356-6185

March 24, 1988

Senator William Cohen
322 Hart Bldg.
Washington, D.C. 20510

Dear Senator Cohen:

I commend your attention to the need for legislation to regulate laboratory testing performed in physician offices and other non-regulated facilities.

Enclosed please find copies of my letter to the Senator from my state, The Honorable John Glenn, and other data pertinent to the need for this vital legislation.

Both as a laboratory professional and as the parent of a child who was the recent victim of erroneous lab results reported from a physician office lab, I urge your continued committment to this legislation. The safety and well-being of the private citizens are in your hands.

Thank you for your consideration and time. If you have any questions, please don't hesitate to call.

Respectfully yours,

Janice N. Meyer

Janice N. Meyer
Clinical Laboratory Scientist,
National Certifying Agency

enclosures
JNM/jm
cc: Rep. Ron Wyden
Congressman John Dingell
Senator David Durenberger

At the state level I am presently working with House Representative Judy Sheerer to have legislation passed in Ohio.

Janice N. Meyer, CLS(NCA)
541 Sandalwood Dr.
Bay Village, Ohio 44140
Ph. 216-356-6185

Senator John Glenn
503 Hart Bldg.
Washington, D.C. 20510

Dear Senator Glenn:

This concerns the Senate Government Affairs Committee's scheduled oversight sessions planned for March 23 and 24 to determine the need for legislation to regulate laboratory testing performed in physician offices.

Both as a laboratory professional and as parent of a one(1) year old child who was the recent victim of erroneous lab results reported from a physician's office , I urge your immediate action on this vital legislation . Voluntary approaches to the problem have not and will not meet with the success necessary to ensure the public safety that is demanded and is rightfully due to the consumer of lab services whereever they are performed. In addition, such regulation can significantly contribute to decreasing the overall cost of healthcare by reducing the volume of needless tests and followup care that is the result of initial erroneous test results. It should also be noted that laboratory tests are used in direct patient management, and regulated(inspected testing facilities) consistently produce more accurate and reliable test results than the non-licensed physician office laboratory(POL).(See attached).

Such legislation must include all POLS regardless of the volume or type of test performed. Often there are references to "minor tests" such as a urinalysis or a hematocrit; there is no such thing as a"minor test". Laboratory tests (especially those performed in POL) are used to make immediate diagnoses and prescribed treatment plans. All laboratory tests must be subjected to rigorous Q.A./Q.C.(Quality Assurance/Quality Control) programs to ensure the accuracy and precision of the test result. Many physician offices now perform an extensive battery of tests and their volumes of tests may rival small hospital laboratories. These testing sites(POLS) may have qualified laboratorians on staff; more often it has proven to be that the physician relys on non-laboratorians (in many instances non-medical family members such as the high school neice. Which ever the case may be all laboratories must meet the same standards and that includes being inspected and licensed.

The longer this problem is "examined" by authorities in a position to correct the inadequacies, the more innocent patients (children, nursing home patients, and the general public) will be subjected to sub-standard testing which can have serious consequences for their health and indeed their lives.

Undoubtedly any attempt to regulate POL testing will be met with much disagreement from physician groups. This seems to be a standard reaction. What they must understand is that this is not an attack on them, but yet a system which will allow them to continue to enjoy the benefits of in-office testing (which include increased revenues to their practice) while significantly reducing the increased liability risks they assume when performing the laboratory tests. 'Not knowing what they do not know' is very hazardous to the patient and to their practice.

Thank you for your time and consideration. Attached please find additional information. If I can be of further assistance, of if you have any questions, please do not hesitate to call.

Respectfully yours,

Janice N. Meyer

Janice N. Meyer
Clinical Laboratory Scientist
National Certifying Agency

enclosures
JNM/jm
cc:Senator William Cohen
Rep. Ron Wyden
Congressman John Dingell
Senator David Durenberger

Janice N. Meyer,CLS(NCA)
541 Sandalwood Dr.
Bay Village, Ohio 44140
Ph. 216-356-6185

Personal Bio:

* Over 10 years experience in the clinical laboratory. Positions held in major healthcare facilities and laboratory services have included consultant, management, and training; and in laboratory diagnostics product Quality Control.

*Contributor to laboratory technical manual utilized nationally

*Co-author of article published in a physician's journal

*Author of article published in newsletter to physician offices

To: All Senators and House Representatives

From: Janice N.Meyer,CLS(NCA)
541 Sandalwood Dr.
Bay Village, Ohio 44140

Subject: The need to regulate laboratory testing in physician offices through legislation to ensure that all labs meet the same standards, and for the protection of the public .

Dear Senators and House Representatives:

I am certain that all of you are aware of the present nationwide concern over the above subject and have read the vast array of articles/publicity addressing the problems and possible solutions. Please allow me to briefly review a few points.

1. Some estimates are that "50% of all outpatient testing is performed in office labs- other reports are that it is not this high, but all agree that the volume has increased and

2. That the volume will continue to increase with a projected "16% growth rate through 1990"

3. "80% of test results from proficiency surveys performed in POL(Physician office labs) were less accurate than from licensed labs."

4. "Greater than 97% of Family Practice and and greater than 90% of Primary Care physicians have office labs ."

5. " A survey conducted in Ohio and N.C. showed that only 47% of Family Practice physicians had a Q.C.(Quality Control) program in their office labs."

6. In dollars and cents,"the POL market represented in 1985 an estimated $300 million" , and by"1990 projections indicate the POL market will be $650 million."

7. Profit margins for physician office laboratories may be as high as 30%-75% even with mandatory assignment from Medicare.

8. All other laboratory facilities (hospital and reference) are required to pass inspections to ensure that Quality Assurance/Quality Control programs are in place; CLIA (Clincal Laboratory Improvement Act. Physician office laboratories which include emergency care centers are currently excluded.

What Can You Do?

Support and Pass legislation to require all laboratories including POL to meet the same standards. The protection of the general public is in your hands

Janice N. Meyer,CLS(NCA)
541 Sandalwood Dr.
Bay Village, Ohio 44140

The following is a personal account of an erroneous lab procedure performed in a physician's office lab. It is presented to you in the hope that it will help you to understand the need for legislation to regulate such testing for the protection of the general public.

A healthy one (1) year old child was recently taken to the pediatrician for his required immunizations and physical. A fingerstick was perfomed by the office staff member to collect a blood sample for a hematocrit, routinely done on all one(1) year olds according to the pediatrician. As a laboratorian I observed that the sample was being collected wrong(diluted with alcohol and with several air bubbles). As the mother of the child and consumer of the services, I asked myself should I correct her then and risk her wrath at being told how to do her job, or wait for the test results? I opted to wait for the test results, and to discuss the problem with the physician.

When the physician came into the room to complete the physical, he entered with the comment that the child was anemic and that he was writing a prescription for iron medication, to keep him on it for 2 weeks and return for follow-up tests; that if the hematocrit was still low he would then start to look into other areas and have additional tests performed. As I am listening to this, I am thinking of how the sample was collected, and that this individual (on staff at a large teaching hospital, graduate of a highly respected medical school) whom I entrust my child's health to is MAKING AN ERRONEOUS DIAGNOSIS, PRESCRIBING AN ERRONEOUS COURSE OF TREATMENT BASED ON ONE SINGLE ERRONEOUS TEST RESULT. The treatment would have put my child on unnecessary medication, and had him return for additonal office lab tests which undoubtedly would have been performed wrong again.

After listening to the physician and his lecture concerning iron rich foods, I calmly (while seething inside) proceeded to tell him that I did not believe the test result and that to confirm my account of the erroneous test sampling, I would be taking my child to a licensed laboratory facility to have the test repeated. He looked at me with disbelief and finally said that just to be sure there was no question about this he would write and order for a battery of tests, CBC, DIFF., and Retic. Count.

After taking my child to a licensed facility and subjecting him to another blood sampling, it was indeed confirmed that he was NOT anemic and infact was in excellent health . All Laboratory test results were normal.

I returned the following day with copies of the test results to the pediatrician's office. Upon presenting him with the test results, I asked him what his diagnosis would be based on these results, he said that of course according to these the child was perfectly fine. I asked him which test results he wanted to accept, his from the office, or the ones from the licensed laboratory. He said of course he would accept the new test results.

I included along with the correct test results, several pieces of information for him and his staff regarding the hazards of office lab testing, and what they could do to improve their skills and knowledge. I also asked him what types of controls and calibrations were performed in his office lab for the test in question. He was very vague in his response and it was very apparent that he actually knew nothing about which I was talking. Several days later he phoned me to tell me that he had discussed the problem with the staff member and that she felt really bad about it, but that she told him she had a really good flow of blood and actually had to hold cotton on the puncture to stop the bleeding. Also he said he had talked with a doctor in the hospital and that the doctor told him that the result produced in his office was probably more accurate than the automated result (the one from the licensed lab), because the automated hemaocrit was a calculated one. As I am listening to all of this, I am even further amazed at how they have all missed the point. The specimen was collected WRONG; having a good blood flow was not at question, the collection of air bubbles and contamination with alcohol, diluting the sample, was the issue. Futhermore, the reasoning of the other physician concerning the calculated hematocrit vs the spun hematocrit done in the office is an issue all unto itself.

All of this led me to believe that the physician still did not fully acknowledge or understand the severity of his error. This is not an isolated incident. Countless reports have been documented of lab errors occuring in unlicensed facilities; errors which have resulted in the hospitilization of patients, and unnecessary blood transfusions being ordered to name a few examples. Fortunately for the patients, many of the errors were discovered by repeat testing done in the licensed facilities laboratory.

What about all the other children subjected to laboratory testing in this pediatrician's office and all other physician offices? What are the percentages of the parent being a trained laboratorian to realize and seek correction of errors? Very small percentages that the parent will be a laboratorian, and very unlikely that any parent will dare to question the doctor. Has the doctor inquestion made efforts to correct the problems in his office testing procedures? Who knows? He doesn't have to answer to anyone. What are the chances of this same type of error occuring in a licensed testing facility? VERY, VERY SMALL and in fact probably not at all. Why? Because,#1. Proper specimen collection procedures are one of the first areas addressed in clinical laboratory training; this is further enforced by written procedure manuals in the laboratory which must be read by each new employee, and by employee orientation procedures in licensed facilities requiring demonstration of proficiency; also additional Quality Control/Quality Assurance programs are in place, including inspections during which many times employees will be observed by the inspecting body to determine their appropriate technique and protocols. #2. A Clinical Laboratory Scientist or a Clinical laboratory Technician is a highly skilled and trained individual whose eye is always watchful for inappropriate specimens. In fact specimens are discarded and recollected if it is determined that for any reason the specimen would produce an inaccurate test result.

What was I billed for the inaccurate test result? $7.00 for the the hematocrit (cost to the physician is less than $2.00), and of course all other cost for the office visit. I of course incurred the full expenses for the complete battery of needless tests he ordered. Did I pay the $7.00? No. In fact I took the charges for the battery of tests into the doctor's office and requested an adjustment on the bill to include these.

Other personal experiences in physician offices have shown that even if they have controls they only run them "when things start to look funny"; and on other occasions office staff have not known the difference between a standard and a control; still others have said that it was too expensive to run controls and others have said they would participate in a proficiency program only if it were mandatory. Repeated cost analysis of laboratory testing shows it highly cost-effective (profitable if you will) even with appropriate Q.C./Q.A. programs.

The above is not an attack on the medical profession nor on any staff member who works in the physician's office. It is presented so that they may acknowledge what they do not know and seek appropriate training. Laboratory testing is a separate specialty and area of expertise.

"Caveat emptor" (buyer beware) was never more applicable than it is to the consumer of laboratory tests from an unlicensed testing facility such as a physician's office or emergency care center. Until legislators address this problem by passing legislation to require all laboratories to meet the same standards, the burden of policing your lab results will lie solely on you, the patient or patient's family.

John R. McKernan, Jr.
Governor

Rollin Ives
Commissioner

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
AUGUSTA, MAINE 04333

PUBLIC HEALTH LABORATORY
Department of Human Services
221 State Street
Augusta, Maine 04333
Telephone (207) 289-2727

March 25, 1988

The Honorable William S. Cohen
Ranking Minority Member
Subcommittee on Oversight of
Government Management
442 Hart Senate Office Building
Washington, D.C. 20510

Dear Sir:

Thank you for offering me this opportunity to submit comments on the clinical laboratory picture in Maine.

Currently, there are two State licensing laws - one for hospitals - the other for independent laboratories. The hospital licensing law as it pertains to laboratories, closely parallels the Medicare conditions for participation and generally accepts Joint Commission on Accrediation of Hospitals (JCAH), American Osteopathic Association (AOA) and College of American Pathologists (CAP) accreditation of these laboratories. The three unaccredited hospital laboratories in Maine are inspected annually under similar regulations for both State licensure and Medicare certification.

Independent laboratories are licensed under the provisions of the Maine Medical Laboratory Act. Including the most recent amendment, it requires not only independent laboratories by Medicare definition but also incorporated laboratories for the mutual use by groups of physicians or group practice owners and laboratories testing for drugs of abuse in the workplace to be licensed. Further, it requires that all physician office and group practice laboratories successfully participate in an approved proficiency testing program. These laboratories would not be licensed, however.

All laboratories are subject to inspection. Licensed laboratories are inspected annually and those subject only to proficiency testing will be inspected randomly to insure compliance with the pertinent regulations (proficiency testing).

State licensing regulations include standards for personnel qualifications, physical facilities, safety, quality control, proficiency testing, specimen handling, laboratory management and ethics. The rationale behind these regulations and licensing in general is to insure that testing is accurately, reliably, and competently performed and records are available to document that these standards are met.

Penalties for non compliance are a fine of $50 - $500 or up to one year imprisonment or both as well as a provision for an injunction through the Attorney General.

The quality of clinical testing in Maine generally varies according to where the testing is performed. It has been my experience that laboratories regulated through licensing, certification or accreditation have the personnel, equipment and policies for quality assurance to produce clinically accurate results. Problems do occur, but tend to be random. For instance, in reviewing proficiency test results transcription errors crop up from time to time and in the past, smaller labs have attempted to perform types of bacteriology which exceed the abilities of the limited laboratory staff. The latter has been resolved by encouraging these labs to refer the more difficult bacteriology to reference labs.

The quality of testing in physicians' office labs (POL's) varies much more widely. POL's have been totally unregulated; trained personnel and quality control policies are frequently non-existent. Methodologies are often obsolete and such basic concepts of good laboratory practice as observing expiration dates of test reagents and kits, keeping meaningful records and properly calibrating and maintaining equipment are neglected either by ignorance or design.

In fairness it should be noted that some POL's are conscientiously operated by qualified personnel and would meet most standards for licensure or certification. However, I have observed a cardboard box with a light bulb used for a bacteriology incubator, an antibiotic susceptibity testing technique which has been obsolete for 20 years, hematology test equipment so dirty that results could be obtained when no specimen was introduced, gonorrhea cultures incubated at a temperature high enough to kill the organisms and uncalibrated thyroid function test equipment removed from the physician's office so specimens could be tested in the lab employee's home.

Medicare/CLIA laboratory inspections are performed for the state agency by trained laboratory surveyors. Technical assistance is available from a consultant at the regional office and an excellent line of communication exists. The inspection process itself is generally satisfactory but if problems occur, the enforcement process is often slow but this could be due to emphasis on higher priority actions elsewhere.

The current system for grading proficiency test results consists of establishing an acceptable range by statistically analyzing the results for each test by method. By definition (after outliers are excluded), 95% of the results closest to the mean (± 2 standard deviations) are acceptable and the remaining 5% (>2 standard deviations) are classified as unsatisfactory. Although this can be a good system for interlaboratory comparison, it does not address the clinical significance of the error. Acceptable ranges based on the clinical significance of the results varying from the true value would be a better gauge of laboratory performance. This system would also weed out less precise methods.

I feel that to improve the system the following should be addressed: (1) Upgrading the surveyors' skills - New technology such as flow cytometry makes it difficult for surveyors to accurately inspect laboratories unless they have received up-to-date training. (2)Assessing necessity of testing - There is a potential for POL's in particular to perform testing more for the revenue generated than for diagnosis and management of clinical conditions. A related issue would be the conflict of interest of physicians having a financial interest in licensed/certified laboratories. (3) Setting minimum standards for testing in POL's - There is a strong argument that all clinical testing should be performed under the same conditions to insure uniform quality of testing but a reasonable first step for POL's would be to apply the Medicare standards for proficiency testing and quality control.

Again, thank you for offering me this opportunity and if I can be of further assistance feel free to contact me.

Sincerely yours,

Michael C Sodano

Michael C. Sodano, Supervisor
Laboratory Improvement Program
Public Health Laboratory

MCS/car
cc/Rollin Ives, Commissioner
Department of Human Services
Dr. Philip W. Haines, Director
Public Health Laboratory

Joint Commission
on Accreditation of Healthcare Organizations

March 2, 1988

Chairman
Subcommittee on Oversight
  of Government Management
Committee on Governmental Affairs
United States Senate
Washington, DC. 20510-6250

Dear Sir:

We are writing in response to your announcement of February 10, 1988 which states your intent to hold hearings March 23 and 24 relative to the federal governnment's role in ensuring the quality of medical laboratory testing. You specifically inquire as to the role of the Joint Commission in this area. Our item-by-item responses are attached.

We trust that the enclosed information is fully responsive to your questions. If you feel we have not adequately addressed these issues or if you have additional questions or concerns, we would be pleased to provide a further response.

Sincerely,

Dennis S. O'Leary, M.D.
President

DSO:cv

Enclosure

cc: The Honorable Carl Levin
United States Senate

The Honorable William S. Cohen
United States Senate

875 North Michigan Avenue
Chicago, Illinois 60611
312/642-6061

Member Organizations
American College of Physicians
American College of Surgeons
American Dental Association
American Hospital Association
American Medical Association

Joint Commission Response
To Questions Raised by
The Subcommittee on Oversight of Government Management
Committee on Governmental Affairs

The Joint Commission Accreditation Process

1.a Please describe the procedures used by the Joint Commission in granting accreditation to hospital labs.

The Joint Commission does not accredit hospital clinical laboratories; rather, the Joint Commission accredits hospitals with integral clinical laboratories. The steps in the accreditation process may be briefly described as follows:

- establishment of hospital accreditation standards, including standards for clinical laboratories;
- differentiation between standards of critical importance to accreditation and those of somewhat less importance;
- establishment of criteria for scoring standards compliance;
- training of hospital accreditation program surveyors ...the basic hospital accreditation survey team includes
    - a physician (with experience as chief of a hospital medical staff)
    - a nurse (masters degree with experience as a hospital nurse administrator)
    - a hospital administrator (masters degree with experience as a hospital chief executive officer)
    - a medical laboratory technologist (certified medical laboratory technologist; nearly all Joint Commission laboratory surveyors are educated at the masters degree level and many at the Ph.D. level);
- conduct of accreditation surveys of applicant hospitals by survey teams;
- report of survey findings to the Joint Commission central office for analysis, review and validation;
- presentation of survey findings to Accreditation Committee of Joint Commission Board of Commissioners;
- rendering of an accreditation decision by the Accreditation Committee, which may include:
    - unencumbered accreditation,

  - accreditation with contingency(ies)--the hospital is advised that its affirmative accreditation is contingent upon correction of one or more significant problems within specified times, or
  - nonaccreditation;

- rendering of an accreditation report advising the hospital of the accreditation decision; and
- if applicable, monitoring of problem resolution by the hospital

1.b Is there a charge to the hospital for Joint Commission Accreditation? If so, please describe the standard charges.

A charge is imposed by the Joint Commission for an accreditation survey. In 1988 the range of charges for a hospital accreditation survey for a general acute care hospital (with less than 75,000 outpatient visits per year) which does not operate a long term care, substance abuse, hospice or rehabilitation center are as follows:

	Hospital w/lab Accredited by the College of American Pathologist (CAP)	Hospital w/lab not Accredited by CAP
Minimum charge	$,5,572	$6,472
Maximum Charge	$30,360	$34,960

2.a. How many Joint Commission-accredited hospital labs are there?

There are 5,198 Joint Commission accredited hospitals. The CAP accredits clinical laboratories in 2,180 of these hospitals. The remaining 3,018 hospitals either have their laboratories surveyed by the Joint Commission or obtain clinical laboratory services under arrangements off-premises. The results of the CAP survey of the clinical laboratory in a hospital seeking Joint Commission accreditation are furnished the Joint Commission and are reviewed by Joint Commission central office. Any CAP findings which reach Joint Commission contingency status are reported to the hospital as an integral of its accreditation report.

2.b. Please indicate how many of these labs participate in Medicare, are covered by CLIA, both or neither.

We believe that all of the non-federal hospitals (4,901) that we accredit participate in Medicare. In addition we estimate that 48 federal hospitals (Indian Health Service) that we accredit also participate in Medicare. Those hospitals that we accredit that obtain clinical laboratory services off-premises, under arrangement, obtain such services from a Medicare certified laboratory. We do not know which of these hospital clinical laboratories are covered by CLIA.

2.c. **How many of these labs are accredited by the College of American Pathologists (CAP)?**

Please refer to our response to question 2.a. above.

3.a. **Please describe the procedures followed in conducting a lab inspection in a Joint Commission accredited hospital lab. Please include sample copies of the check lists and other forms used in the inspection process.**

As noted in our response to question 1.a. above, the Joint Commission does not accredit laboratories; rather we accredited hospitals. As an integral of this process we either employ a Joint Commission laboratory surveyor to examine the hospital's integral laboratory(ies), (or non-hospital laboratory operated on the hospital's premises) or rely on information provided us concerning the CAP findings with respect to such laboratories. At our meeting with your staff on February 18, 1988 we provided a copy of the form (Survey Report Form - SRF) used by the Joint Commission in the Survey of a hospital's laboratory(ies), a copy of our clinical laboratory surveyor scoring guidelines, and a copy of the Accreditation Manual for Hospitals - 1988 (AMH '88). The latter document, as the name implies, contains Joint Commission accreditation standards for hospitals including those applicable to the hospital's laboratory(ies).

3.b. Do inspectors go beyond forms used in the inspection process. If so, please give examples.

Joint Commission surveyors generally do not address issues which are not literally or implicitly covered by accreditation standards in connection with the survey of a hospital's clinical laboratory. The surveyors do conduct education sessions for laboratory staff and provide consultation and advice.

3.c. How often does the Joint Commission inspect labs?

A hospital receiving an unencumbered accreditation, i.e. accreditation without an attendant contingency, is ordinarily surveyed by the Joint Commission once every three years. Hospitals receiving accreditation contingent upon correction of one or more specific problems within a specified time period are subject to on-site re-evaluation by one or more Joint Commission surveyors. Such hospitals would be visited more frequently than once every three years. In the thirteen-month period ending December 31, 1987, the Accreditation Committee of the Joint Commission rendered 2,600 hospital accreditation decisions. In 741 instances, or 30% of the time, the decision of the committee involved accreditation contingent upon evidence of problem correction to be verified by an on-site follow-up visit.

The following data relative to Joint Commission experience with the Clinical Laboratory portion of hospital accreditation is provided for your information.

Hospital Accreditation Contingencies
Arising from
the Clinical Laboratory Component of the Joint Commission Survey
(893 Survey)
1986

Generic Problems	Contingency - Numbers of Decisions			
	Contingency Report		Contingency Visit	
	No.	Percent	No.	Percent
Laboratory Proficiency Testing	20	41	11	22
Quality Control	16	33	15	29
Administrative Procedures	7	14	12	23
Safety	4	8	7	14
Professional Staff	2	4	6	12
Total	49	100	51	100
Percent of Surveys Yielding Contingency	5.5%		5.7%	
(716 Surveys) 1987				
Laboratory Proficiency Testing	27	42	11	28
Quality Control	17	27	14	35
Administrative Procedures	9	14	10	25
Safety	6	9	3	7
Professional Staff	5	8	2	5
Total	64	100	40	100
Percent of Surveys Yielding Contingency	8.9		5.6	

3.d. Are labs given advance notice of inspections? If so what is the timing of this notice.

Hospitals are ordinarily provided notice of all accreditation surveys from four to six weeks in advance of the scheduled visit.

3.e. What are the qualifications of the individuals who conduct the Joint Commission inspections? How many inspectors participate in an on-site inspection?

Please refer to our response to question 1.a. above.

4.a. How does the Joint Commission determine that a lab has failed inspection?

The hospital clinical laboratory which obtains a score of 3 (partial standards compliance), 4 (minimal standards compliance), or 5 (noncompliance) in any of the asterisked items in the clinical laboratory section of AMH '88 will accrue a contingency in connection with its accreditation decision. That is, the hospital's accreditation will be contingency upon evidence (within a specified period of time) that the noted problem(s) has been corrected. Failure of a hospital to achieve correction of such problems will result in the loss of the hospital's accreditation.

4.b. If there are written standards in addition to the check list referred to in 3. above, please provide them to the Subcommittee.

The SRF provided Subcommittee staff on February 18, 1988 contains all the accreditation standards applicable to hospital clinical labs.

4.c. Please give examples of situations or conditions that would cause an inspector to fail a lab.

Statistics concerning the frequency with which hospitals incur accreditation contingencies as a result of the Joint Commissions survey of their laboratories and the generic problems involved are supplied at question 3.c. above.

4.d. For each of the last five years, please identify the labs which have failed inspection or have been cited for deficiencies.

Please refer to our response to question 3.c. above with respect to the numbers of hospitals receiving accreditation contingencies related to Joint Commission surveyor clinical laboratory findings. Data for the past five years are not on our computer and hence are not available.

4.e. What action does the Joint Commission take when a lab fails inspection or is cited for deficiencies?

Please refer to our response to query 3.c. above. It should be noted while approximately 15% of the hospital labs that we survey yield a contingency in connection with the hospital's accreditation, nearly 100% of clinical labs we survey receive recommendations for improvement.

4.f. Please identify what action was taken for each of the labs identified above which failed inspection or which was cited for deficiencies.

Over the past five years staff can recall only two instances where a hospital was notified of an impending nonaccreditation decision arising from its failure to effect timely correction of cited clinicial lab problems. In both instances, the hospital effected the needed corrections. There has yet to be an instance where a hospital failed to correct a clinical laboratory problem disclosed as an integral of the accreditation process.

5.a What sort of information does the Joint Commission provide to HCFA on Medicare and CLIA labs (both CAP-accredited and not) in the Joint Commission hospitals that have failed inspection or been cited for deficiencies?

The Joint Commission provides no specific data to HCFA concerning laboratories in accredited hospitals. Hospitals inspected by HCFA as a result of a complaint (pertaining to said hospital) or on a random sample validation survey basis are required by Section 1865 of the Social Security Act to authorize the Joint Commission to provide HCFA a copy of its most recent accreditation report. The Joint Commission provides these reports (including clinical laboratory findings contained therein) to HCFA.

5.b. What sort of information does the Joint Commission provide to HCFA on a routine basis about the outcome of inspections of Medicare and CLIA labs (both CAP-accredited and not) in Joint Commission hospitals?

The Joint Commission provides the following information to HFCA on a routine basis:

- the Joint Commission hospital survey schedule;
- the results (hospital accreditation or nonaccreditation) of the deliberations of the Joint Commission Accreditation Committee; and
- on a case by case basis, information as to whether the clinical laboratory in a particular hospital was surveyed by CAP or the Joint Commission.

Proficiency Testing

1. How many labs in Joint Commission hospitals participate in the CAP proficiency testing series? How many participate in other proficiency testing programs?

We estimate that between 70 and 80 percent of laboratories in Joint Commission accredited hospitals participate in CAP proficiency testing. All of the laboratories in Joint Commission accredited hospitals participate in proficiency testing.

2. Does the Joint Commission accept the accuracy level determined by the organization administering the proficiency testing? If not, what does the Joint Commission consider an acceptable level of accuracy for proficiency testing? Does this level vary by laboratory specialty--clinical chemistry, hematology, microbiology, etc.?

The Joint Commission accepts the accuracy level determined by the organization administering the proficiency testing.

3. How many labs in Joint Commission hospitals failed their proficiency tests in the following laboratory specialities: microbiology, immunology/serology, clinical chemistry, hematology, immunohematology,

toxicology, virology, cytology, histology, other specialities (please specify)? Please identify those labs which failed. Has the proportion of labs failing in a particular specialty increased or decreased in the past five years? Is there a correlation between the labs that fail and the organization conducting the proficiency testing program.

The Joint Commission maintains no records which reveal the specific nature of hospital problems connected with specific proficiency testing programs. You will note from our response to question 3.c. above that "proficiency testing" generically is the leading reason for clinical laboratory contingencies in connection with hospital accreditation decisions.

4. How does the Joint Commission determine that a lab has failed a proficiency test in a particular specialty? What action has the Joint Commission taken against those labs which failed a proficiency test? Is this data reported to HCFA for Medicare and CLIA labs?

The Joint Commission accepts the accuracy level determined by the organization administering the proficiency testing in assessing a hospital's clinical laboratory performance. The critical factor for the Joint Commission in this regard is how the hospital has addressed this evidence of a problem, i.e. what has the institution done to address the identified problem, to prevent its recurrence, and to subsequently monitor the area to make certain the problem does not recur. The major problem cited by the Joint Commission in the generic area of proficiency testing problems is the hospital's failure to take appropriate action in connection with adverse proficiency testing results. As noted in response to question 3.c. above, proficiency testing problems result in hospital accreditation decisions attended by a contingency requiring evidence of corrective action within a specified period of time. Data surrounding hospital clinical laboratory proficiency testing problems are not reported to HCFA.

5. What data is provided to HCFA on a routine basis about the performance of Medicare and CLIA labs in Joint Commission hospitals?

Please refer to reply to query 5.b above.

6. Using Joint Commission or other data, has the Joint Commission done any analysis of the accuracy of test performed by clinical labs? Please provide copies of such studies or statistics.

The Joint Commission has not performed any analysis of the accuracy of tests performed by clinical labs.

COLLEGE OF AMERICAN PATHOLOGISTS /

WASHINGTON OFFICE
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March 11, 1988

The Honorable William S. Cohen
Ranking Minority Member
Subcommittee on Oversight
of Government Management
United States Senate
439 Hart Office Building
Washington, DC 20510-6250

Attention: Mary Gerwin

Dear Senator Cohen:

The College of American Pathologists (CAP) is pleased to respond to your February 2, 1988, request for information regarding the CAP's Laboratory Improvement Programs. In addition to the responses below, please find enclosed a copy of our March 2, 1988 testimony before the U.S. House of Representatives Subcommittee on Regulation and Business Opportunities which gives an overview of CAP's four decades of leadership in laboratory improvement (hereinafter cited as "background document"); a 1988 Surveys Notebook containing extensive information regarding the CAP Surveys (Proficiency Testing) programs; and a Laboratory Accreditation Program (LAP) Notebook which provides comprehensive information regarding the LAP program. For the sake of simplicity, we will repeat your questions in the same numerical order submitted, followed by our answers.

THE CAP ACCREDITATION PROCESS:

(1) Please describe the procedures used by CAP in granting accreditation to clinical labs. Is participation in a proficiency testing program a condition of CAP accreditation? What is the charge to the lab for CAP accreditation?

CAP Response:

The procedures used by CAP in granting accreditation are outlined in the enclosed background document beginning in Paragraph 3, page 14 through Paragraph 4 on page 16 and in the Laboratory Accreditation Program Orientation booklet on pages 3 through 6. Additional information and examples of the standards and checklists used in the inspection process are included in the Standards for Laboratory Accreditation, the Inspectors Manual, and the fourteen LAP Checklists provided in the LAP Notebook.

As outlined in the LAP Standards on page 9, "The pathology service shall regularly participate in the College of American Pathologists Interlaboratory Comparison (Surveys) program based on the type of testing the laboratory regularly provides."

Accreditation fees are billed annually for ongoing participation in the program. The participation fee covers all costs of inspection and continuous accreditation. Fees are determined by the number of checklist sections and charges are made according to the following schedule for each laboratory applying for accreditation. Generally a checklist section applies to a specific laboratory discipline or department. Special function laboratories are charged $200 per year provided they are inspected at the same time as the main laboratory. Satellite laboratories and special function laboratories are considered separate laboratories and must complete a separate set of application materials.

CAP Laboratory Accreditation Program Fees

1-4 Checklist Sections	$ 275.00 per year
5-8 Checklist Sections	$ 410.00 per year
9-12 Checklist Sections	$ 525.00 per year
13+ Checklist Sections	$ 575.00 per year*

* plus $ 50.00 per additional section.

(2) How many labs participate in the CAP accreditation program? Please categorize these labs in two ways: whether a lab is an independent, a hospital, or a physician's office lab; whether it is participating in Medicare, is covered by CLIA, both or neither. Please provide this information for each of the past five years. Are any labs that are CAP accredited also accredited by the Joint Commission on Accreditation of Hospitals (JCAH)? If so, how many?

CAP Response:

As of February 19, 1988, 4,040 laboratories were enrolled in the CAP Laboratory Accreditation Program. A demographic breakdown of types of laboratories is provided in Tab 7, page 3 of the background document. In recent years, the number of laboratories using their

CAP Laboratory Accreditation Program participation to meet requirements of CLIA 1967 were:

1/1/85	353
1/1/86	352
1/1/87	418
1/1/88	450

Data for previous years is not readily available. Since CAP does not have "deemed status" under Medicare, we do not maintain records indicating how many CAP accredited laboratories also participate in Medicare. Please see discussion in Paragraph 5, Page 13 through Paragraph 2 on Page 14 of the background document.

JCAH estimates that approximately 2,400 of its 5,300 accredited hospital laboratories use their participation in the CAP Laboratory Accreditation Program in lieu of inspection by the JCAH.

(3) Please describe the procedure followed in conducting a CAP inspection. Please include sample copies of the check lists and other forms used in the inspection process. Do inspectors go beyond the information required on the check lists? If so, please give examples. How often does CAP inspect labs? Does this vary by type of lab? Are labs given advance notice of inspections? If so, what is the timing of such notice? What are the qualifications of the individuals who conduct the CAP inspections? How many CAP inspectors participate in an on-site inspection?

CAP Response:

The procedure used in conducting the inspection is outlined in the background document beginning in Paragraph 3, Page 14 through Paragraph 4, Page 16. Also, more detailed information is presented on pages 1-11 in the Inspectors Manual and on pages 1-6 of the Laboratory Accreditation Program Orientation in the LAP Notebook.

Sample copies of each of the CAP Laboratory Accreditation Program Checklists are included in the LAP Notebook.

The Checklists serve as the basis for the inspector's evaluation of a Laboratory's compliance with the Standards. The inspector would deviate from the checklists to obtain further clarification regarding an issue which may be subject to questions on whether the laboratory is in compliance. For example, question 01.0510 queries "Is there a system whereby the identity of the analyst performing or completing the test can be established in all instances (computer-generated reports as well as conventional reporting systems)." Frequently, examination of a patient report will not establish compliance with this requirement. Consequently, examination of a series of examples of laboratory documentation may be necessary to ensure that appropriate systems are in fact in place.

CAP performs onsite inspections every two years with a required self-evaluation occurring during interim years. Please see Paragraphs 1-3 on Page 16 of the background document. Generally 30 to 60 days advance notification is provided for an impending inspection. Please see Paragraph 5, Page 14 of the background document.

The inspection team leaders are drawn from the more than 2,000 volunteer pathologists trained in the inspection process. The inspection team also may include doctoral scientists, medical technologists, or other physicians depending on the nature of the laboratory services to be reviewed. Attempts are made to tailor the composition of each inspection team to provide a "Peer Review" of the laboratory's services. The number of inspectors will vary from one to as many as is needed to conduct a thorough review of the laboratory. The average team size is 4.4 persons. On an average, the CAP conducts 5.5 inspections daily. See Paragraph 3, Page 14 in the background document and Paragraphs 1-3, Page 1 in the Inspectors Manual for additional information regarding team composition.

(4) How does CAP determine that a lab has failed inspection? If there are written standards in addition to the check list referred to in 3, above, please provide them to the Subcommittee. Please give examples of situations or conditions that would cause a CAP inspector to fail a lab. For each of the last five years, please identify the labs which have failed inspection or have been

> cited for deficiencies. What action does CAP take when a lab fails inspection or is cited for deficiencies? Please identify what action was taken for each of the labs identified, above, which failed inspection or was cited for deficiencies.

CAP Response:

A more detailed overview of the process used to determine if a laboratory meets the Standards for Laboratory Accreditation can be found on Pages 15 and 16 of the background document and Pages 4-12 of the Inspectors Manual. Briefly however, the inspection team performs an indepth review of the laboratory operations using the appropriate LAP Checklists. Every question in the Checklist which is pertinent to the operation of the inspected laboratory must be answered. All "Phase II" questions must be satisfactorily complied with prior to award of accreditation. (Phase II deficiences are those which directly affect patient care and/or safety.) Lack of proper documentation of such compliance with any Phase II question, presence of large numbers of Phase I deficiencies or repetition of the same Phase I or Phase II deficiencies over subsequent inspections can result in denial of accreditation. Examples of the hundreds of Phase II questions can be found throughout the fourteen checklists by looking under the column heading "Phase".

Once the laboratory has completed the inspection process and documented correction of deficiencies, the Regional Commissioner of the LAP will recommend to the Commission on Laboratory Accreditation that accreditation be granted. If corrections are not completed within a reasonable time, the Regional Commissioner will recommend that the laboratory be denied accreditation. In any case, the entire Commission approves accreditation decisions.

Pursuant to CAP procedure, without prior authorization of the participant, CAP does not release specific information regarding an individual laboratory's performance. Where authorized, information regarding a laboratory's loss of accreditation (or correction of deficiencies) consistently has been provided to the appropriate private, state and federal accrediting and licensure organizations at the time such action was taken.

On the average, one to five laboratories fail to achieve accreditation annually. Many more voluntarily select not to undergo the accreditation process or withdraw at some time during the process. Since almost every laboratory will have some deficiency at the time of inspection, it is impossible to provide individual information on each laboratory's deficiencies and its responses for each occurrence over the last five years. Please see Paragraphs 3-5, Page 15 of the background document for further information in this regard.

As previously noted, copies of the Standards and other supporting accreditation materials are included in the LAP Notebook.

(5) In the case of CLIA labs, is information on labs which have failed inspection or which have been cited for deficiencies provided to HCFA?

CAP Response:

In those cases where laboratories using the CAP Laboratory Accreditation Program for CLIA exemption have failed to meet the Standards for Laboratory Accreditation, the CDC and/or HCFA have been notified of such situtations. Where requested, deficiency information on CAP Laboratories using participation for CLIA exemption has been provided to the appropriate federal agency.

PROFICIENCY TESTING

Please provide the following information about CAP's proficiency testing program:

(1) How many labs of each type (independent, hospital, physician office lab; Medicare, CLIA, combined, neither) participate in the proficiency testing program? If available, please provide this information for each of the past five years. How many of these labs are certified by JCAH?

CAP Response:

Approximately 12,000 hospital and independent laboratories participate in CAP Surveys. Another 2,000 participate in the CAP EXCEL Surveys. The CAP also provides specimens and data processing for approximately 1300 participants (primarily physician office laboratories) in the American Society for Internal Medicine Medical Laboratory Evaluation Program (ASIM/MLE). Please review the graphs and tables in Tab 2 and Tab 5 of the background document for further demographic breakdown of laboratories by type participating in CAP Surveys (information for 1985 was not readily retrievable in the manner presented in Tab 5).

We do not distinguish whether participation is to meet CLIA or Medicare requirements except for the 450 laboratories using CAP Laboratory Accreditation for CLIA exemption. However, except for the physician office laboratories, we would expect that most of the laboratories participating in CAP Surveys are using one or more of their subscriptions to meet private, state, or federal requirements since thousands of copies of individual participant reports are submitted quarterly to such agencies. Please see Paragraphs 2-4, Page 6 of the background document. Also, we do not know how many of the 5300 JCAH laboratories participate in CAP Surveys, but would expect that a significant number of them do.

(2) How often do labs receive proficiency test samples? Does this vary by lab type? Does this vary by the particular proficiency test series?

How large is the proficiency test sample; i.e., how many specimens does a lab test of a particular kind? Does this vary by lab type or the particular proficiency test series?

How does CAP assure the quality of its proficiency testing samples? How is the nature of the sample (i.e., presence or absence of substance, amount of substance present) determined before sending it to the lab?

CAP Response:

Generally laboratories receive proficiency testing samples on a quarterly basis. However, some programs are shipped on a different schedule due to program types and rarity (expense) of program materials. Schedules are not varied because of laboratory types. Please see the Surveys shipping schedule, the 88 Surveys Brochure, and the EXCEL Brochure included in the Surveys Notebook for more detailed information regarding shipping frequency for each Survey.

Surveys samples are custom prepared to meet CAP specifications as designed by the experts on the 16 CAP Resource Committees. Each sample is specifically prepared to meet its intended use. Sizes of samples and configuration of specimens vary accordingly. It should be emphasized that the extensive number and comprehensive scope of CAP Surveys are the result of efforts to tailor programs to meet the needs of the complex array of different types of laboratories rather than attempting to force all laboratories into a single rigid set of materials which do not correlate with their particular mode of practice.

For example, the Comprehensive Chemistry Survey described on page 9 of the 88 Surveys brochure includes one 3 mL specimen for ammonia, two 3 mL specimens for cholesterol and triglycerides, one 3 mL specimen for HDL cholesterol and two 10 mL specimens (each in duplicate) containing normal and abnormal levels for the other 30 analytes present in each quarterly shipment. In addition, in 1988 one quarterly shipment will include a "pilot" sample to test the feasibility of adding an extra 10 ml vial of bicarbonate buffer to allow for testing of CO_2 content. The extra smaller vials for specific analytes are necessitated because increased concentrations of some analytes will cause "matrix interferences" or distorted values with other analytes if present in the same vial. Other "proficiency testing" programs frequently do not address the complexity of matrix interferrences or system biases to the extent as do the CAP Resource Committees.

Although the Comprehensive Chemistry Survey represents the basic or core analytes tested in most chemistry laboratories, the CAP provides 24 additional chemistry Surveys including different analytes, different matrices (blood, urine, spinal fluid, etc.), and different vial sizes to allow laboratories to tailor the programs to most nearly match their specific testing patterns to the analytes included in their Surveys programs. No other proficiency testing service provides a comparable spectrum of analytes or flexibility of services as that in CAP Surveys (Please see Pages 5-6 of the background document, the 88 Surveys Brochure and the Surveys Manuals in the Surveys Notebook for more extensive information regarding the configuration of the CAP Surveys).

Except in rare instances where commercial technology is unavailable and services of research facilities must be obtained, CAP Surveys specimens are prepared to meet CAP specifications by well-known diagnostic manufacturers. These manufacturers are required to adhere to Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) established by the Federal Drug Administration (FDA). This is in contrast to most state and former federal programs in which many specimens were prepared in public health laboratory environments without any requirements for meeting FDA GMP requirements. Specimen validity is certified by quality assurance steps in the manufacturing process, through referee and/or reference laboratory examination when needed, and by rigorous review of the interlaboratory comparison data by the Resource Committees of the CAP.

(3) CAP administers different proficiency tests for different lab specialties. For each of the last five years, for each of the proficiency test series CAP administers, please answer the following:

How many labs participate in the series?

What is the charge to the lab to participate in the proficiency test series?

What does CAP consider an acceptable level of accuracy for each proficiency test series?

How many labs failed the proficiency tests within each CAP series? Please identify those labs which failed. Has the proportion of labs failing a particular series increased or decreased in the past five years?

Please provide information on the acceptable level of results for a particular test within a specialty (e.g., ± 10 percent). What is the criteria for the range or level of acceptable difference?

CAP Response:

The Surveys Enrollment Table for the years 1974 through 1988 in Tab 2 of the background document presents information regarding subscription levels for each CAP Survey for those years.

The CAP Surveys Pricing Table in Tab 2 of the background document presents comparative pricing for each Survey for the last 5 years. It should be noted that CAP attempts to maintain the medical relevance of challenges in each Survey, introducing new challenges and deleting old challenges where appropriate. Consequently Surveys are reconfigured on an annual basis to meet the changing scope of services for the respective laboratory populations and therefore, some prices may vary accordingly from year to year.

Over the last 25 years, acceptable accuracy levels and methods of establishing these levels have evolved commensurately with the evolution of the technology of the laboratory procedures. The level of accuracy achievable for each analyte in each Survey is defined by more than 100 expert physician and doctoral scientist members of the CAP Resource Committees. Selected from the leading experts within each medical discipline, no comparable cadre of scientific expertise has ever been amassed to provide regular review and input into a proficiency testing service. Listings of these individuals is provided in the front of each of the Surveys Manuals for the medical disciplines represented.
For the 13 analytes where definitive methods are available at the National Bureau of Standards, acceptable accuracy levels are established by methods which compare well with these methods. For other procedures, a comparative method is selected for establishing desired accuracy levels. A comparative method is one which generally has historically demonstrated reliability and is considered widely compatible with most current methods; in some instances, this is the "all participant mean".

For many analytes, evaluation criteria are based on fixed limits which are medically relevant or technically achievable ranges. These are based on the therapeutic or diagnostic use of the test. For some procedures, grading criteria are defined as statistic limits (e.g., 2 standard deviations of participant results). In all cases, acceptable ranges of accuracy are determined after review by medical experts.

Discussion of evaluation criteria for the analytes in each of the Surveys can be found in the "Guidelines for Evaluation", "Special Evaluation Criteria" and "How to Interpret the Evaluation Report" sections within each of the Surveys Manuals. Due to the extensive array of scientifically developed techniques for assessment of acceptable accuracy levels for the more than 300 procedures in CAP Surveys, we have chosen not to iterate each of them here since each is documented in the previously referenced sections of the manuals. However, it should be emphasized that the methods used by the CAP have been reviewed by state and federal personnel repeatedly and found to be not only acceptable but also equivalent to or more stringent than those used by the federal and or state systems.

Consistent with CAP procedure, when authorized, information regarding individual laboratory performance has been provided to the appropriate state, private and federal monitoring organizations. To retrospectively determine how many labs failed to perform acceptably on each Surveys analyte for each Survey series for each shipment over the last five years would represent an overwhelming data processing task which (if data is still available) would be financially and logistically impractical and could not be completed within the timeframe allowed for preparation of this response. In Tabs 3 and 4 of the background document, sample data recently collated for another congressional committee is provided. We trust this will be sufficient to demonstrate the positive trends observed through participation in these programs.

Participant performance across all Surveys continues to improve. Samples from the previously cited data and information provided in the articles referenced in the extensive bibliography of publications regarding Surveys data included in Tab 1 of the background document verify these trends.

As noted previously, criteria for acceptable performance on Surveys analytes are outlined in the respective sections of the Surveys Manuals.

(4) How does CAP determine that a lab has failed a proficiency test series? What action has CAP taken against those labs which failed a proficiency test series? Is this data reported to HCFA for Medicare and CLIA labs?

CAP Response:

Generally a laboratory does not "fail a proficiency test series" per se. Usually a laboratory's performance on a given analyte or multiple analytes will fall outside acceptable limits. Determination of such deficiencies of performance is according to the evaluation criteria described earlier. Under circumstances where the participant is using his participation to meet some agency or organization's proficiency testing requirements and has authorized release of his results, a record of performance is provided to the appropriate monitoring agency. It should be noted that it usually is a requirement of the monitoring agency that the participant must authorize release of the data. At this time the agency will assume responsibility for follow up action according to its perscribed operational protocols.

If a laboratory is using its Surveys participation to meet CAP Laboratory Accreditation requirements, reports of the laboratory's performance are provided to the LAP Regional Commissioner for the region in which the laboratory is located. The Regional Commissioner will review the laboratory's performance and determine if a deficiency is a random occurance or if it is indicative of a trend. Based on this determination, the Regional Commissioner may require a response from the laboratory on what corrective action has been taken to ensure quality care to patients. If the response is satisfactory, no further action is taken unless subsequent deficiencies occur. If performance problems remain uncorrected or documentation is unsatisfactory, the Regional Commissioner may require an interim onsite validation inspection or may initiate actions to rescind the laboratory's accreditation. However, it should be emphasized that in all cases of aberrant performance, upon receipt of the performance report, LAP accredited laboratory directors are required to take corrective action and document such corrections for review at the time of the next onsite inspection or for submission to the Regional Commissioner upon request. Regularly, correspondence and follow up actions are being handled by Regional Commissioners across the U.S. for laboratories in the CAP Laboratory Accreditation Program.

As noted earlier, where authorized by the participant, copies of individual participant reports routinely are provided either in hard copy and or on magnetic media to the various state agencies, CDC, HCFA, or their designees.

(5) Has CAP done any analysis on the level of accuracy of tests performed by clinical labs using CAP data or other data? Please provide copies of such studies or statistics.

CAP Response:

The CAP Commission on Scientific Resources (Resource Committees) annually hosts a CAP Conference on Selected Topics. These conferences usually relate to the "state of the art" in some area of laboratory testing and use CAP Surveys data in development of the presentations. The publication from the 1986 conference, Quality Assurance in Physician Office, Bedside and Home Testing, has been provided to the Subcommittee staff. Although often quite technical, copies of the proceedings from the previous thirteen conferences can be provided.

CAP Resource Committee members regularly publish information relating to laboratory performance and trends observed from Surveys data in Archives of Pathology and Laboratory Medicine as well as in other scientific journals. A listing of some of these is included in the bibliography presented in Tab 1 of the background document. The manuscripts from the 1987 CAP Conference on "The Evaluation of Proficiency Testing Results for Quantitative Methods in Relation to Clinical Usefulness" will be published in the April Archives of Pathology and Laboratory Medicine and, when available, can be provided to the Subcommittee Staff upon request.

A copy of Data ReCAP which summarizes CAP Surveys participant peformance on selected analytes for the decade ending in 1980 has been provided to the Subcommittee Staff. Selected updates of this data requested by the House Subcommittee on Regulation and Business Opportunities is included in the background document in Tabs 3 and 4. Descriptions of these tables and graphs is presented on pages 7-11 in the background document. Also,two articles describing the effect of participation in CAP Laboratory Improvement Programs are included in Tab 6.

The CAP appreciates the opportunity to work with the Senate Subcommittee on Oversight of Government Management and trusts the materials provided will be of assistance in your deliberations regarding quality of laboratory services and the effectiveness of the federal role and private sector initiatives in assuring quality patient care. We look foward to the opportunity to testify before your Subcommittee on March 24. If we can provide further assistance, please do not hesitate to contact Al Ercolano, Director of our Washington Office.

Sincerely,

William B. Zeiler, MD
William B. Zeiler M.D.
President, College of American Pathologists

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

AUG 14 1987

The Honorable William S. Cohen
Ranking Minority Member
Subcommittee on
Oversight of Government Management
Committee on Government Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Senator Cohen:

This correspondence is in response to your July 16, 1987, request for information concerning the Health Care Financing Administration's (HCFA's) role in regulating clinical laboratories engaged in interstate commerce under the Clinical Laboratories Improvement Act (CLIA) and participating in Medicare.

Prior to 1979, the Centers for Disease Control (CDC) was responsible for regulating clinical laboratories under CLIA, and HCFA was responsible for the approval of clinical laboratories for Medicare payment purposes. Following the implementation of an interagency agreement between HCFA and the Public Health Service (PHS) in 1979 to promote coordination of Federal laboratory activities, HCFA became responsible for the administration of the CLIA program. The CLIA licensure process was phased into the Medicare survey and certification program because most CLIA laboratories are also Medicare participants.

Currently, Medicare approved and CLIA licensed laboratories are surveyed by Medicare State agencies and survey findings are forwarded to HCFA regional offices for final determinations concerning CLIA licensure and/or Medicare approval. Laboratory surveys are conducted using Medicare forms and survey procedures, because personnel, recordkeeping and quality control requirements are essentially the same for the two programs. Clinical laboratories approved for Medicare are also considered approved for Medicaid payment purposes. We believe that this information may be helpful in interpreting the enclosed materials.

You requested that we supply information in response to a number of specific questions. The detailed answers are enclosed.

If additional information is needed, please contact Thomas G. Morford, Director, Health Standards and Quality Bureau, on 301/597-2750.

Sincerely,

William L. Roper

William L. Roper, M.D.
Administrator

Enclosure

RESPONSE TO INFORMATION REQUESTED

(1) How many laboratories are currently licensed under the Clinical Laboratories Improvement Act of 1967?

Currently, 1456 laboratories are licensed under CLIA.

(a) How many of these laboratories have been approved through their participation in the College of American Pathologists' inspection/proficiency testing program?

In addition to the 1456 laboratories licensed under CLIA, there are 415 laboratories accredited by the College of American Pathologists' (CAPs') Laboratory Accreditation Program that have been granted an exemption from licensure under CLIA.

(b) How many are approved through their participation in the Joint Commission on Accreditation of Hospitals accreditation program?

The Joint Commission on Accreditation of Hospitals (JCAH) has not applied for recognition of its program for CLIA exemption from licensure purposes. However, most of the laboratories exempted from CLIA by virtue of their CAP accreditation are located in JCAH hospitals.

(2) How many laboratories since 1980 have been cited for failure to meet the CLIA standards? Please provide annual statistics for the years 1980 to 1986, including the names of the laboratories, the reason for the citation and the sanctions imposed on the cited laboratories.

Deficiencies for Failure to Meet CLIA Standards Cited During Onsite Surveys:

Information in our data system includes laboratories approved for Medicare participation and licensed under CLIA for the current and three prior surveys. Enclosed are Individual Facility Profiles (IFPs) available for CLIA licensed laboratories with deficiencies cited for the current and three prior surveys (TAB #1). Deficiencies were cited in 874 laboratories for the current survey and in 842, 781 and 693 laboratories for the three prior surveys. The IFP includes: the name of the laboratory that had deficiencies cited at the time of the survey; the specific deficiency or citation; and the deficiency status code. The survey information located at the bottom left corner of the IFP displays nine (9) characters and the positions are defined as follows:

Position	Definition
1-4	Health and safety regulation data tags as listed on the Laboratory Survey Report Form (TAB #2) with CLIA regulatory requirements referenced to Code of Federal Regulations, Part 74 (TAB #3);
	Numeric Deficiency Code:
5-9	5 - No Date or Plan of Correction 6 - Plan of Correction 7 - Date of Correction 8 - Waiver/New Date of Correction 9 - Refused to Correct;
6-9	Julian Date, beginning with the year in the sixth position, and the seventh - ninth positions indicating the deficiency code status date.

The Medicare adverse action status of the laboratory is indicated in the upper left corner.

CLIA adverse actions are as follows:

CLIA Adverse Actions

Unsatisfactory Proficiency Testing (PT) Performance by CLIA Licensed Laboratories

Failures in CDC's PT program are provided as summary data from 1979 to 1986. CDC's PT program was discontinued in August 1986. When CDC's program was in operation, laboratories that were determined to have an unsatisfactory PT performance during the above period were sent notices proposing to exclude the unsatisfactory tests from their CLIA licenses. These exclusions were referred to as licensure limitations or revocations. However, the CLIA statute does not permit licensure limitations or revocations until the laboratory has been sent a notice concerning the proposed limitation and had an opportunity for a hearing before an administrative law judge (ALJ). Therefore, laboratories requesting hearings often continued to perform the tests in which their PT performance was unsatisfactory.

The notice to the laboratory also asked the facility if it wished to continue in CDC's PT program for the unsatisfactory tests and if it wanted a hearing. If the laboratory requested a hearing and asked to remain in CDC's PT program, and demonstrated through its PT performance that it could perform the previously failed tests satisfactorily, the proposed licensure limitation was withdrawn and the hearing did not take place.

If the laboratory did not respond to the proposed notice or, if it did, and agreed with the proposed notice, a second notice was sent informing the laboratory that its license was limited and that it could no longer perform the unsatisfactory test(s) in interstate commerce.

If the hearing was held and the ALJ's decision upheld the Secretary's limitation proposal, the unsatisfactory tests were excluded from the license for 1 year or until the laboratory exhibited satisfactory performance in CDC's PT program.

In the following table, ALJ decisions are reflected as either limitations or withdrawals of proposed actions. Withdrawals were usually initiated by the Secretary because the laboratories' PT performance improved while the hearing was pending.

The amount of time between initial notices and final ALJ decisions frequently exceeded 1 year; therefore, the annual statistics presented under limitations or withdrawals reflect ALJ decisions on previous years' initial notices.

Dates	Initial Notices	Limitations Imposed	Withdrawals
9/79 - 12/81	151	64	44
1/82 - 12/82	103	42	14
1/83 - 6/83	116	16	11
7/83 - 6/84	222	90	62
7/84 - 6/86	260	78	108

In addition, laboratory-specific information for PT failures for 1980-1986 is provided on the enclosed list of laboratories licensed under CLIA (TAB #4). The encircled laboratories had their licenses revoked by test or category due to unsatisfactory PT performance in one or more test procedures.

License Revocations

The laboratories in TAB #5 were sent a notice to revoke the entire CLIA license based on deficiencies cited during an onsite survey and, in some cases, unsatisfactory PT performance. The license was either involuntarily revoked or the laboratory withdrew from the CLIA program.

(3) How many complaints about laboratory practice or performance has HCFA received since 1980?

(a) What was the nature of the complaints?
(b) How many complaints spurred action such as an investigation by HCFA or another appropriate agency?
(c) What action was taken?

HCFA regional offices have information on 29 complaints related to laboratory services. All of the complaints were investigated and the following information is provided:

Number of Complaints	Nature of Complaint	Action Taken
1	Use of expired blood products	Hospital terminated based on deficiencies other than laboratory services.
7	Questionable test results	No adverse action taken.
11	Unqualified/unsupervised/ nonlicensed staff	1 potential termination but facility corrected deficiencies. 10 - no adverse action taken.
1	Hospital accepting test results from uncertified lab	Referred to Program Operations for payment action.
2	Poor sample handling/improper sample collection	No adverse action.
1	Hepatitis danger to employees	No adverse action.
1	Records not maintained	Deficiencies cited and laboratory took corrective action.

2	Billing improprieties	No adverse action. 1 case referred to Office of the Inspector General.
1	Inappropriate test reporting	Deficiencies cited. Laboratory took corrective action.
1	Inappropriate handling of waste	Complaint not substantiated.
1	Patient developed blood poisoning after venipuncture	Complaint not substantiated.
29	TOTAL	

In addition to the general complaints described above, we are including information on transfusion-related fatalities since they are handled in the same manner as complaint investigations. As a result of a Memorandum of Understanding between HCFA and the PHS, HCFA is responsible for the review of transfusion-related fatalities occurring in Medicare approved facilities. Specifically, the health care facility sends an incident report concerning the particular fatality to the Food and Drug Administration (FDA) and FDA forwards the information to HCFA for necessary action. Since 1980, HCFA has received 108 reports from FDA. All 108 incident reports have been administratively reviewed. Ninety-three of the fatalities were investigated by onsite inspection by either a HCFA regional office or a State agency (SA) inspector and 6 are pending an onsite investigation. Of the 93 investigations completed, all facilities were determined to be in compliance with the conditions of participation or took acceptable actions to correct cited deficiencies with the exception of one facility that agreed to voluntarily terminate its transfusion services. In addition, 11 facilities initiated disciplinary action, terminated employment or secured resignations of staff members; in one facility, the SA referred the personnel involved to the State Medical Board/State Board of Nursing; in two facilities HCFA's Office of Medical Review was asked to review physician practices and one accredited hospital was placed under SA monitoring.

SAs also receive and investigate complaints on an ongoing basis. HCFA regional offices review SA complaint investigation records as part of their State Agency Evaluation Programs (See 7b).

(4) How many HCFA staff members are assigned to monitor the performance and quality of interstate laboratories?

HCFA has assigned 15.3 full time equivalents (FTEs) to monitor interstate as well as Medicare laboratories. This includes 5.3 FTEs allocated for the administration of the CLIA program by HCFA's central office and its regional offices and 10 FTEs allocated for the purpose of conducting Federal monitoring surveys by HCFA's regional offices. Additionally, there are 156 SA surveyors who conduct onsite inspections of CLIA and Medicare laboratories for HCFA.

a. How much money does HCFA spend for such personnel, staff and support costs? Please provide annual data from FY 1980 to FY 1986.

Year	Amount Spent
1980	$ 7.65M
1981	6.46M
1982	2.99M
1983	5.40M
1984	7.16M
1985	7.19M
1986	6.71M

(These data include the amounts paid to States to conduct surveys for HCFA for both Medicare and CLIA purposes as well as costs related to the standards enforcement activities of Federal staff.)

(5) How many laboratories receive Medicare reimbursement for laboratory services? Please provide statistical information that breaks the numbers into laboratory categories, i.e., independent laboratory, hospital laboratory, physician's office laboratory.

As of June 30, 1987, there are 6,658 hospital laboratories and 4,368 independent laboratories that are approved and therefore eligible for Medicare payment. For hospitals, laboratory services are included as part of the hospital's overall prospective payment regardless of whether the laboratory testing is performed by the hospital or referred to another laboratory. We have no figures on the number of physicians' office laboratories that receive Medicare reimbursement. However, in a 1982 Report of the Laboratory Task Force, HCFA estimated that 80,000 to 100,000 physicians perform laboratory tests in their own offices.

(6) How much money has Medicare spent for laboratory services, annually, from FY 1980 to FY 1986?

The information available is for calendar years 1979 and 1985 (see TAB #6).

(7) How much has HCFA spent annually in payments to the States to provide services to regulate Medicare laboratories for the years FY 1980 to FY 1986?

Year	Amount Spent	Survey Coverage Level*
1980	$ 7.1M	100%
1981	5.9M	83%
1982	2.4M	35%
1983	4.7M	50%
1984	6.4M	50%
1985	6.4M	60%
1986	5.9M	50%

*denotes the percentage of total laboratory surveys paid by HCFA

(a) How many laboratories are regulated by the States using funds provided by HCFA?

The States, with funds provided by HCFA, survey approximately 4,588 laboratories: 220 CLIA licensed; 3,132 Medicare approved, and 1,236 which are both CLIA licensed and Medicare approved. In addition, the States are responsible for investigating complaints received on laboratories that are Medicare approved, CLIA licensed and/or accredited by an organization whose standards have been determined to meet the Federal requirements (JCAH for Medicare, CAP for CLIA). States also survey a random sample of laboratories to monitor approved accrediting organizations' application of the Federal health and safety standards.

(b) Does HCFA monitor the State inspection of laboratories?

HCFA monitors the performance of SAs by conducting Federal monitoring surveys on a sample of laboratories surveyed by SAs and comparing results. In FY 1986 approximately 160 such surveys were conducted nationally, representing more than 10 percent of all Federal monitoring surveys. In addition, the States' performance of all administrative and operational aspects of their survey and certification functions/activities are monitored by the regional offices on an ongoing but planned cyclical basis via the State Agency Evaluation Programs mentioned under 3.

(8) Please provide any reports issued by HCFA or a description of any reports now underway by HCFA on the quality and performance by clinical laboratories.

There have been several studies and reports either that have been issued or are in progress in which HCFA was either the originating component or was a participant in the study or report. These include:

- A study on clinical laboratory standards commissioned by the Assistant Secretary for Planning and Evaluation of the Office of the Secretary (ASPE) which was completed in April 1986. The contractor for the project, Macro Systems, carried out the following tasks in performing the study and analysis:

  (1) Reviewed current Federal clinical laboratory requirements in conjunction with selected State requirements and private, voluntary standards to determine: a) areas of substantial agreement; b) conflicting standards or requirements; and c) omissions in regulatory coverage which may have important public health consequences, either with respect to types of standards employed or settings in which standards are enforced;

  (2) Assessed current Federal clinical laboratory requirements to determine their actual role in protecting the public health and the costs incurred;

  (3) Reviewed and analyzed data concerning the impact on clinical laboratory practice of changes in laboratory reimbursement policies;

  (4) Reviewed and analyzed data concerning the impact of technological advancements on costs, quality, and settings of laboratory services; and forecast future impact of technological changes on laboratory services; and

  (5) Based upon the four tasks above, identified and evaluated possible alternatives to current regulatory requirements that hold promise for effectively assuring high levels of laboratory performance while reducing costs or holding costs at acceptable levels.

This "Final Report on Assessment of Clinical Laboratory Regulations" is available from ASPE:

- Section 9303 of the Consolidated Omnibus Budget Reconciliation Act of 1985 directed the Secretary of Health and Human Services to report to Congress on the standards that might be established under the Medicare program for clinical laboratories which are part of, or associated with, a physician's office to assure the health and safety of individuals on whom the laboratories perform clinical diagnostic laboratory tests for which payment may be made under the program. In preparing the report HCFA reviewed information available from the literature, HCFA data bases, a variety of private sector organizations, SAs and other sources. The information reviewed considered the scope and quality of physicians' office laboratory testing, types of personnel performing the tests, State and private sector regulatory programs for physicians' offices and the costs associated with various regulatory approaches. The report is currently being reviewed within the Health Standards and Quality Bureau prior to circulation to the Department and release to the Congress;

- HCFA performed two reviews of reports received by the Department concerning fatal transfusion reactions (TABS #7 and #8). The reports are required by FDA as a part of the regulations promulgated under the Biologics Act. As part of the Memorandum of Understanding between HCFA and FDA, HCFA agreed to follow-up on reports of fatal transfusion reactions forwarded to HCFA by FDA. HCFA has authority over the total facility if it is in either the Medicare program or Medicaid program. FDA's authority is limited to the blood bank, whereas HCFA may inspect the entire hospital, long term care facility, laboratory or other health care facility. The reports from FDA and the onsite follow-up investigations by HCFA are reviewed in order to assess the causes of the transfusion deaths, develop survey procedures for use by the onsite inspection teams and to prevent recurrences. The survey procedures were issued in 1986 and HCFA is in the process of updating its analysis. Survey procedures have been provided to the JCAH for its use in developing private sector accreditation programs. HCFA has also published the results of the 1983 findings in one of the laboratory journals and the findings of the 1983 and 1985 surveys have been presented at various professional meetings;

- A study was performed by personnel from HCFA central office and the Boston Regional Office on the types of deficiencies observed during onsite inspections of independent laboratories and how these deficiencies might indicate the need for private sector training programs as well as revisions in the regulations to improve quality. The findings of this study were published in summary form and the findings are being incorporated into the proposed revisions of the Medicare and CLIA regulations (TAB #9); and

- HCFA commissioned a study by the American Society of Cytology (TAB #10) to develop guidelines for the survey of cytology laboratories and to make recommendations which could be used in revising the Medicare and CLIA regulations. The study was commissioned in 1981 and provided the agency with several indicators and guidelines which could be used in the survey process. HCFA is also in the process of soliciting proposals for a contract to survey cytology laboratories and to revise clinical laboratory guidelines, regulations and surveyor training courses based on the survey findings. Cytology is a highly specialized area of the laboratory which requires specific expertise and knowledge to properly evaluate testing and reporting. Since the majority of individuals performing Medicare and CLIA surveys have limited expertise in cytology and the testing is subjective in nature, HCFA is seeking assistance under this contract in the performance of cytology surveys and in developing the appropriate changes in regulations and survey procedures.

(9) When were the CLIA regulations most recently reviewed by HCFA?

HCFA, on an ongoing basis, has been reviewing the CLIA regulations and developing as well as revising regulatory guidelines since 1978 when HCFA became responsible for administration of the CLIA program. HCFA has developed CLIA licensure procedures and published instructions to its regions and States over the period 1978 - 1987. In addition, the following regulatory revisions were proposed or are in process:

- In 1979, HCFA and CDC jointly revised clinical laboratory personnel standards and published a notice in the Federal Register concerning personnel standards for all clinical laboratories. However, these proposed standards were withdrawn when public comments reflected a lack of consensus on the proposed changes;
- In 1984, CDC published a notice requesting comments from the public on possible mechanisms for revision of the clinical laboratory standards based on a consensus development process. The comments received by CDC are being considered in the current process of revising all clinical laboratory regulations. As a part of this process CDC and HCFA have also been developing and revising PT requirements for clinical laboratories, including CLIA laboratories, and have had a public meeting on PT standards in Atlanta this year; and
- Overall, HCFA is currently preparing a major revision of all of the clinical laboratory standards, including the CLIA standards, to develop uniformity between the Medicare and CLIA programs, delete obsolete standards, provide for new technologies, increase regulatory flexibility and provide for more outcome oriented measures of quality assurance.

(10) Please list the regulations that have been issued by HCFA that pertain to the standards imposed on interstate and Medicare laboratories.

The three regulatory revisions listed below pertain to Medicare approved laboratories:

- September 19, 1974--Conditions for Coverage of Services of Independent Laboratories. Also see September 19, 1976 revision relating to Histocompatibility Testing included in the enclosure (TAB #11);

- August 14, 1981--Conditions of Participation for Hospitals Conditions of Coverage of Services of Independent Laboratories; Immunohematological Testing, Transfusion Services and Bloodbanking. This revision relates to HCFA's adoption of the FDA blood banking regulations for Medicare laboratories (TAB #12); and

- June 17, 1986--HCFA published revised Conditions of Participation for Hospitals which included a revision of the standards for laboratory services in hospitals. The regulations for laboratories in skilled nursing facilities which are cross-referenced to the hospital regulations were also revised at the same time (TAB #13).

SUBCOMMITTEE NOTE:

Tabs/Appendices are retained in Subcommittee files.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

MAR 16 1988

The Honorable William S. Cohen
United States Senate
Washington, D.C. 20510

Dear Senator Cohen:

Thank you for your letter of February 26 in which you requested information concerning clinical laboratories approved to participate in the Medicare program and licensed under the Clinical Laboratories Improvement Act (CLIA). Enclosed is our response to your specific questions.

I would be glad to supply any further information you may require. An identical response has been provided to Senator Carl Levin under separate cover.

Sincerely,

William L. Roper

William L. Roper, M.D.
Administrator

Enclosure

RESPONSES TO INFORMATION REQUESTED

1. Q Using the format provided below, please indicate the number of CLIA-only, Medicare only, and joint CLIA-Medicare labs for which HCFA is responsible. Please include those labs exempted from CLIA through CAP and those labs in Joint Commission hospitals deemed under Medicare. Also include in the Joint Commission hospital lab count those labs in Joint Commission hospitals that are accredited by CAP.

	CLIA Only		Medicare only		CLIA and Medicare			
	CAP	Non-CAP	Joint	Non-Joint	CAP	Non-CAP	Joint	Non-Joint
1983								
1984								
1985								
1986								
1987								

1. A. Charts 1 through 5 list the number of CLIA only, Medicare only and dual CLIA Medicare laboratories for the years 1983 through 1987. Included are national numbers, regional numbers, and numbers for each subcommittee member's state. The charts are footnoted to explain the types of laboratories counted under each cateogory. The number of CAP accredited laboratories in Joint Commission accredited hospitals is not included in these charts because this information is not routinely received from the Joint Commission for inclusion in our automated data system.

Footnotes for Charts 1 through 5

[1] Includes non-Medicare approved independent laboratories with CAP exemptions in lieu of CLIA license.

[2] Includes non-Medicare approved independent laboratories with CLIA licenses.

[3] Includes laboratories in accredited hospitals (Joint Commission and American Osteopathic Association (AOA)). There were 93 AOA accredited hospitals in 1987. (Ninety-nine percent of accredited hospitals perform laboratory services onsite.)

[4] Includes independent labs (of which there were 4492 in 1987) and nonaccredited hospitals labs. (Ninety-nine percent of the nonaccredited hospitals perform laboratory services onsite.)

[5] Includes Medicare approved hospital and independent labs with CAP exemptions in lieu of CLIA license.

[6] Includes Medicare approved hospital and independent labs with CLIA license.

[7] Includes accredited and nonaccredited hospital laboratories that also have CLIA licenses or CAP exemptions. Our records for laboratories with CLIA licenses or CAP exemptions do not differentiate those that are located in accredited and nonaccredited hospitals.

* Our automated data system and manual records do not differentiate the types of laboratories that fall in these categories for years 1983-1986.

** Our automated data system and manual records do not capture this information for the years 1983-1986.

LABORATORIES

Chart No. 1

1987	CLIA Only		Medicare Only		CLIA and Medicare			
	CAP 1/	Non-CAP 2/	Joint 3/	Non-Joint 4/	CAP 5/	Non-CAP 6/	Joint 7/	Non-Joint 7/
National	33	197	5227	5915	443	1312	465	465
Region I	0	5	307	361	26	124	45	45
ME	0	0	44	13	1	4	1	1
NH	0	0	31	16	2	5	4	4
Region II	0	7	441	512	6	55	14	14
Region III	0	29	531	526	52	210	92	92
DE	0	2	10	16	0	4	0	0
PA	1	13	266	290	21	74	26	26
VA	0	5	121	49	8	29	14	14
Region IV	6	32	992	912	78	210	73	73
FL	2	3	238	269	11	38	6	6
GA	1	9	139	151	8	40	12	12
TN	2	6	138	101	22	36	16	16
Region V	8	41	999	744	84	210	97	97
MI	1	9	195	140	3	50	14	14
OH	4	11	206	159	27	54	30	30
Region VI	3	31	686	813	42	142	29	29
AR	1	2	64	78	7	6	3	3
NM	1	6	40	44	5	11	5	5
Region VII	3	6	325	409	52	113	53	53
Region VIII	1	15	184	296	33	57	31	31
Region IX	3	26	593	1087	29	150	19	19
Region X	6	5	169	254	41	43	20	20
AK	0	0	14	17	0	0	0	0

LABORATORIES

Chart No. 2

1986	CLIA Only CAP 1/	 Non-CAP 2/	Medicare Only Joint 3/	 Non-Joint 4/	CLIA and Medicare CAP 5/	 Non-CAP 6/	 Joint 7/	 Non-Joint
National	*	*	5166	5675	409	1298	*	*
Region I			310	360	23	**		
ME			44	12	1			
NH			30	18	2			
Region II			444	513	6			
Region III			529	526	48			
DE			10	16	0			
PA			266	289	18			
VA			119	51	8			
Region IV			954	833	72			
FL			221	231	10			
GA			131	130	8			
TN			133	100	23			
Region V			1003	753	76			
MI			198	157	3			
OH			207	153	27			
Region VI			657	817	36			
AR			59	82	6			
NM			37	46	4			
Region VII			330	403	48			
Region VIII			179	286	29			
Region IX			588	1020	29			
Region X			172	249	42			
AK			14	19	0			

LABORATORIFS

Chart No. 3

1985	CLIA Only		Medicare Only		CLIA and Medicare			
	CAP 1/	Non-CAP 2/	Joint 3/	Non-Joint 4/	CAP 5/	Non-CAP 6/	Joint 7/	Non-Joint 7/
National	*	*	5161	5569	369	1292	*	*
Region I			312	336	24	**		
ME			44	11	1			
NH			28	17	3			
Region II			459	450	7			
Region III			525	453	43			
DE			10	13	0			
PA			112	236	17			
VA			53	55	6			
Region IV			955	798	65			
FL			220	226	9			
GA			133	133	7			
TN			131	100	21			
Region V			1004	771	66			
MI			197	167	3			
OH			209	156	23			
Region VI			640	770	34			
AR			59	81	5			
NM			30	48	4			
Region VII			326	400	40			
Region VIII			182	284	25			
Region IX			586	1035	26			
Region X			172	242	39			
AK			14	18	0			

LABORATORIES

Chart No. 4

1984	CLIA Only 1/ CAP	 2/ Non-CAP	Medicare Only 3/ Joint	 4/ Non-Joint	CLIA and Medicare 5/ CAP	 6/ Non-CAP	 7/ Joint	 7/ Non-Joint
Region I			309	319	23	**		
ME			43	11	1			
NH			28	15	3			
Region II			473	419	6			
Region III			520	435	38			
DE			10	13	0			
PA			266	228	16			
VA			110	51	6			
Region IV			938	806	53			
FL			217	219	8			
GA			130	137	6			
TN			130	92	13			
Region V			997	744	62			
MI			202	169	3			
OH			203	141	20			
Region VI			628	741	31			
AR			59	80	5			
NM			26	52	3			
Region VII			330	407	38			
Region VIII			179	275	22			
Region IX			587	1021	23			
Region X			165	260	38			
AK			12	21	0			

LABORATORIES

Chart No. 5

1983	CLIA Only		Medicare Only		CLIA and Medicare			
	CAP 1/	Non-CAP 2/	Joint 3/	Non-Joint 4/	CAP 5/	Non-CAP 6/	Joint 7/	Non-Joint 7/
National	*	*	5073	5263	286	1205	*	*
Region I			304	295	23	**		
ME			41	11	1			
NH			28	13	3			
Region II			456	415	5			
Region III			504	403	28			
DE			10	11	0			
PA			259	208	12			
VA			109	48	3			
Region IV			913	747	44			
FL			213	200	6			
GA			122	129	6			
TN			118	82	13			
Region V			1008	715	53			
MI			210	163	2			
OH			202	130	17			
Region VI			619	733	29			
AR			59	73	5			
NM			26	52	3			
Region VII			321	410	33			
Region VIII			180	274	20			
Region IX			603	1012	18			
Region X			165	247	38			
AK			12	18	0			

2(a) Q Using the most recent survey information available in HCFA's Medicare/Medicaid Automated Certification System (MMACS), nationally and by region for all labs listed under question in #1, above, (1) how many and (2) what per cent:

-- were reported to have no deficiencies in any conditions?

-- were reported to have a deficiency in at least one condition?

-- had deficiencies in three or more conditions?

Please list for each condition the number and per cent of labs which did not meet that specific condition (frequency and per cent for each code: 405.1311--E24, 405.1312--E26, 405.1313--E28, 405.1314--E31, 405.1315--E55, 405.1316--E62, 405.1317--E86).

2(a) A The condition level citations listed in your letter (4015.1311=E24, 405.1312=E26, 405.1313=E28, 405.1314=E31, 405.1315=E55, 405.1316=E62, and 405.1317=E86) are independent laboratory condition level regulations and condition level E tag numbers from the independent laboratory survey report form. The condition level regulation for laboratory services in hospitals is 482.27. Under this condition, standard level requirements at 482.27(e), (b) and (f) are cross referred to the independent lab requirements at 405.1314(a), 405.1316 and 405.1317. These independent laboratory requirements are only standard level requirements for hospital laboratories.

Chart 6 lists the number and percentage of independent labs which were cited with condition level deficiencies and the number of non-accredited hospital labs which were cited with deficiencies under 482.27 (e), (b), and (f) which are standards under the hospital laboratory regulations that cross refer to the independent laboratory conditions of 405.1314(a), 405.1316 and 405.1317.

Data for Medicare only independent laboratories and Medicare independent/CLIA laboratories are included in the numbers under the independent laboratory category on charts 6 through 15. These numbers do not reflect deficiency data for CLIA only laboratories because MMACS is not programmed to capture data for CLIA only labs (of which there are 197), or deficiency data on accredited hospital laboratories because these facilities are not routinely surveyed by State survey agencies and we do not routinely receive survey data from the accreditation organizations.

Chart No. 6

LABORATORIES WITH CONDITION LEVEL DEFICIENCIES CITED DURING THE MOST CURRENT SURVEY

- -	No Conditions				At Least One Condition				Three or More Conditions			
	Independent' Labs		Nonaccredited Hospital Labs		Independent' Labs		Nonaccredited Hospital Labs		Independent' Labs -		Nonaccredited Hospital Labs	
National	4271	94%	1184	82%	~~[illegible]~~ 250	6%	~~[illegible]~~ 256	18%	40	1%	32	2%
Region I	318	92%	0		26	8%	0		2	1%	0	
ME	7	100%	0		0		0		0		0	
NH	15	100%	0		0		0		0		0	
Region II	435	91%	39	87%	43	9%	6	13%	7	1%	0	
Region III	456	94%	40	91%	29	6%	4	9%	7	1%	1	2%
DE	17	100%	0		0		0		0		0	
PA	269	98%	0		5	2%	0		2	1%	0	
VA	43	96%	3	50%	2	4%	3	50%	0		1	17%
Region IV	630	96%	249	95%	28	4%	13	5%	3	0%	2	1%
FL	224	97%	37	95%	6	3%	2	5%	0		1	2%
GA	82	99%	57	97%	1	1%	2	3%	0		0	
TN	75	95%	22	96%	4	5%	1	4%	0		0	
Region V	530	91%	110	67%	52	9%	53	33%	4	1%	4	2%
MI	114	88%	8	89%	16	12%	1	11%	1	1%	0	
OH	132	93%	0		10	7%	0		0		0	
Region VI	491	95%	181	60%	24	5%	123	40%	5	1%	21	7%
AR	39	95%	31	84%	2	5%	6	16%	0		0	
NM	25	96%	16	89%	1	4%	2	11%	0		0	
Region VII	172	96%	211	92%	8	4%	20	8%	2	1%	0	
Region VIII	115	93%	167	91%	8	7%	16	9%	1	1%	1	1%
Region IX	968	97%	89	96%	31	3%	4	4%	8	1%	2	2%
Region X	156	99%	83	83%	1	1%	17	17%	1	1%	1	1%
AK	7	100%	9	90%	0		1	10%	0		0	

'Includes deficiency data on Medicare-only independent laboratories and Medicare independent/CLIA laboratories.

Chart No. 7 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency	Nation	Region I	ME	NH
Facility Total	4474	346	8	15
E24 Compliance with State and Local Laws	31*	4 1%	-	-
E26 Laboratory Director	57 1%	5 1%	-	-
E28 Supervision	94 2%	8 2%	-	-
E31 Test performed	51 1%	10 2%	-	-
E55 Technical Personnel	31*	2*	-	-
E62 Management	49 1%	1*	-	-
E86 Quality Control	74 1%	8 2%	-	-

* - Less Than 1%.

Chart No. 8   2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency		Nation	Region II
	Facility Total	4474	467
E24	Compliance with State and Local Laws	31*	1*
E26	Laboratory Director	57 1%	9 1%
E28	Supervision	94 2%	17 3%
E31	Tests Performed	51 1%	4*
E55	Technical Personnel	31*	5 1%
E62	Management	49 1%	21 4%
E86	Quality Control	74 1%	18 3%

* - Less than 1%.

Chart No. 9 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency		Nation	Region III	DE	PA	VA
	Facility Total	4474	481	16	275	43
E24	Compliance with State and Local Laws	31*	4*	-	-	2 4%
E26	Laboratory Director	57 1%	8 1%	-	2*	-
E28	Supervision	94 2%	15 3%	-	4 1%	-
E31	Test performed	51 1%	1*	-	-	-
E55	Technical Personnel	31*	1*	-	1*	-
E62	Management	49 1%	4*	-	-	-
E86	Quality Control	74 1%	8 1%	-	2*	-

* - Less Than 1%.

Chart No. 10 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	4474	646	226	81	79
E24 Compliance with State and Local Laws	31*	1*	-	-	-
E26 Laboratory Director	57 1%	10 1%	2*	2 2%	1 1%
E28 Supervision	94 2%	16 2%	5 2%	2 2%	1 1%
E31 Test performed	51 1%	6*	1*	-	1 1%
E55 Technical Personnel	31*	6*	1*	-	1 1%
E62 Management	49 1%	5*	1*	-	-
E86 Quality Control	74 1%	5*	2*	-	-

* - Less Than 1%.

Chart No. 11 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency	Nation	Region V	MI	OH
Facility Total	4474	581	131	141
E24 Compliance with State and Local Laws	31*	9 1%	8 6%	-
E26 Laboratory Director	57 1%	6 1%	2 1%	1*
E28 Supervision	94 2%	18 3%	5 3%	2 1%
E31 Test performed	51 1%	5*	2 1%	2 1%
E55 Technical Personnel	31*	10 1%	8 6%	-
E62 Management	49 1%	3*	1*	1*
E86 Quality Control	74 1%	14 2%	-	4 2%

* - Less Than 1%.

Chart No. 12 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency	Nation	Region VI	ARK	NM
Facility Total	4474	500	42	26
E24 Compliance with State and Local Laws	31*	4*	-	-
E26 Laboratory Director	57 1%	5 1%	1 2%	-
E28 Supervision	94 2%	9 1%	-	-
E31 Test performed	51 1%	9 1%	-	-
E55 Technical Personnel	31*	1*	-	-
E62 Management	49 1%	5 1%	-	1 3%
E86 Quality Control	74 1%	10 2%	-	-

* - Less Than 1%.

Chart No. 13 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	4474	181	122	995
E24 Compliance with State and Local Laws	31*	1*	2 1%	5*
E26 Laboratory Director	57 1%	3 1%	2 1%	8*
E28 Supervision	94 2%	3 1%	2 1%	5*
E31 Test Performed	51 1%	1*	1*	13 1%
E55 Technical Personnel	31*	2 1%	-	3*
E62 Management	49 1%	1*	1*	8*
E86 Quality Control	74 1%	-	2 1%	7*

* - Less Than 1%.

Chart No. 14 2(a)(2)

INDEPENDENT LABORATORIES WITH SPECIFIC CONDITIONS OF COVERAGE OUT OF COMPLIANCE AT THE TIME OF SURVEY

Deficiency		Nation	Region X	AK
	Facility Total	4474	155	7
E24	Compliance with State and Local Laws	31*	-	—
E26	Laboratory Director	57 1%	1*	—
E28	Supervision	94 2%	1*	—
E31	Tests Performed	51 1%	1*	—
E55	Technical Personnel	31*	1*	—
E62	Management	49 1%	-	—
E86	Quality Control	74 1%	1*	—

* - Less than 1%.

Chart No. 15

NONACCREDITED HOSPITAL LABORATORIES WHICH DID NOT MEET THE STANDARD OF MANAGEMENT, PROFICIENCY TESTING AND QUALITY CONTROL DURING THE MOST CURRENT SURVEY

	Laboratory[1] Management		Proficiency[2] Testing		Quality[3] Control		Total Number of Laboratories
National	110	7%	90	6%	197	13%	1443
Region I	0	0	0	0	0	0	16
ME	0	0	0	0	0	0	6
NH	0	0	0	0	0	0	1
Region II	3	7%	1	2%	1	2%	45
Region III	1	2%	3	7%	3	7%	43
DE	0	0	0	0	0	0	0
PA	0	0	0	0	0	0	14
VA	1	16%	2	33%	3	50%	6
Region IV	2	1%	3	1%	9	3%	263
FL	1	2%	1	2%	1	2%	40
GA	0	0	0	0	2	3%	59
TN	0	0	0	0	0	0	23
Region V	20	12%	5	3%	40	25%	163
MI	0	0	1	10%	2	20%	9
OH	0	0	0	0	0	0%	18
Region VI	66	21%	50	16%	113	36%	306
AR	0	0	4	10%	6	16%	37
NM	0	0	1	6%	1	6%	18
Region VII	2	1%	16	6%	4	1%	232
Region VIII	7	3%	3	1%	9	5%	183
Region IX	4	4%	2	2%	2	2%	92
Region X	5	5%	7	7%	16	16%	100
AK	0	0	0	0	1	10%	10

[1] This is a standard level requirement for a hospital laboratory which cross refers to the independent laboratory condition level requirement at 405.1316.

[2] This is a standard level requirement for a hospital laboratory which cross refers to the independent laboratory condition level requirement at 405.1314(a).

[3] This is a standard level requirement for a hospital laboratory which cross refers to the independent laboratory condition level requirement at 405.1317.

(b) Q Looking at the standards and factors within the management condition, 405.1316 (codes E63-E85), (1) how many and (2) what per cent of labs:

-- met every standard and factor?

-- did not meet at least one standard or factor?

-- did not meet three or more standards or factors?

Please list for each standard and factor within the management condition the number and per cent of labs which did not meet that specific standard and factor (frequency and per cent for each code, E63-E85).

(b) A Chart 16 lists the number and percentage of independent laboratories which were cited with standard and factor level deficiencies within the management condition, 405.1316 (codes E63 - E85), and the number of nonaccredited hospital labs which were cited for deficiencies under 482.27(b), which is a standard under the hospital laboratory regulations that cross refers to the independent laboratory management condition (405.1316).

Data for Medicare only independent laboratories and Medicare independent/CLIA laboratories are included in the numbers under the independent laboratory category on charts 16 through 24. These numbers do not reflect deficiency data for CLIA only laboratories because MMACS is not programmed to capture data for CLIA only labs (of which there are 197), or deficiency data on accredited hospital laboratories. Accredited facilities are not routinely surveyed by our state survey agencies and we do not routinely receive survey data from the accreditation organizations.

Charts 17 through 32 list the number and percentage of laboratories which did not meet specific standards and factors within the independent laboratory condition of management during the most recent survey.

(c) Q Looking at the standards and factors within the quality control condition, 405.1317 (codes E87-E95), (1) how many labs and (2) what per cent of labs:

-- met every standard and factor?

-- did not meet at least one standard or factor?

-- did not meet three or more standards or factors?

LABORATORIES WITH STANDARD AND/OR FACTOR LEVEL DEFICIENCIES
WITHIN THE MANAGEMENT CONDITION (405.1316) CITED DURING THE MOST CURRENT SURVEY (E63-85)

Chart No. 16

	No Standard or Factor Level Deficiencies				At Least One Standard or Factor Level Deficiency				Three or More Standard or Factor Level Deficiencies			
	Independent[1] Labs.		Non-accredited Hospital Labs.		Independent[1] Labs.		Non-accredited Hospital Labs.		Independent[1] Labs.		Non-accredited Hospital Labs.	
National	2170	48%	1080	74%	2362	52%	379	26%	486	11%	70	5%
Region I	76	22%	24	92%	269	78%	2	8%	109	32%	1	4%
ME	2	29%	5	83%	5	71%	1	17%	0		0	
NH	3	20%	1	100%	12	80%	0		0		0	
Region II	167	35%	45	100%	312	65%	0		95	20%	0	
Region III	299	61%	41	93%	189	39%	3	7%	36	7%	1	2%
DE	8	47%	0		9	53%	0		1	6%	0	
PA	213	77%	14	100%	63	23%	0		3	1%	0	
VA	32	70%	6	100%	14	30%	0		0		0	
Region IV	428	65%	171	65%	230	35%	91	35%	22	3%	10	4%
FLA	146	64%	34	83%	84	36%	7	17%	4	2%	0	
GA	65	78%	40	68%	18	22%	19	32%	1	1%	0	
TN	59	75%	17	74%	20	25%	6	26%	1	1%	0	
Region V	204	35%	146	91%	381	65%	15	9%	70	12%	2	1%
MI	42	32%	11	100%	89	68%	0		24	18%	0	
OH	38	27%	18	100%	104	73%	0		16	11%	0	
Region VI	202	39%	228	74	313	61%	80	26%	57	11%	18	6%
AR	6	15%	31	82%	35	85%	7	18%	19	46%	1	3%
NM	7	27%	15	83%	19	73%	3	17%	5	19%	1	6%
Region VII	116	64%	135	57%	64	36%	100	43%	10	6%	25	11%
Region VIII	66	53%	132	70%	58	47%	56	30%	5	4%	9	5%
Region IX	515	52%	91	99%	485	48%	1	1%	80	8%	0	
Region X	97	61%	67	68%	61	39%	31	32%	2	1%	4	4%
AK	3	43%	7	70%	4	57%	3	30%	0		1	10%

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[1] Includes deficiency data on Medicare only independent laboratories and Medicare independent/CLIA laboratories.

Chart No. 17 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION I	Maine	New Hampshire
Facility Total	4474	346	8	15
E63 Procedure Manual	1072 23%	165 47%	3 37%	12 80%
E64 Facilities	109 2%	14 4%	-	-
E65 Proper Storage of Chemicals and Solvents	75 1%	13 3%	-	-
E66 Control of Temp. and Humidity	95 2%	18 5%	-	-
E67 Monitored and Recorded Voltage Levels	96 2%	11 3%	-	-
E68 Adequate Fire Precautions	598 13%	116 33%	3 37%	5 33%
E69 Collection of Specimens	30*	2*	-	-
E70 Sterilization	9*	2*	-	-
E71 Sterilization and Disinfection Techniques	100 2%	8 2%	-	-
E72 Disposable Items	121 2%	14 2%	-	-
E73 Device Assuring Proper Sterilization	68 1%	8 2%	-	-
E74 Operation of Autoclave	139 3%	14 4%	-	-
E75 Examination and Reports	123 2%	27 7%	-	-
E76 Reference Specimens	3*	-	-	-
E77 Specimen Records	168 3%	16 4%	-	-
E78 Data for Test Performed	337 7%	67 19%	-	-
E79 Records	87 1%	13 3%	2 25%	1 6%
E80 Copies/Records are Filed	81 1%	18 5%	-	-
E81 Terminology of Tissue Pathology Rpt	2*	-	-	-
E82 Patient Receives Results by Written Consent	36*	2*	-	-
E83 Pertinent Normal Ranges Available	46 1%	11 3%	-	-
E84 List of Analytical Methods Maintained	86 1%	26 7%	-	-
E85 Outside Laboratory Notified and Meets Conditions	124 2%	21 6%	-	-

* - Less than 1%

Chart No. 18 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH
DEFICIENCIES WITHIN THE CONDITION OF
MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION II
Facility Total	4474	467
E63 Procedure Manual	1072 23%	137 29%
E64 Facilities	109 2%	25 5%
E65 Proper Storage of Chemicals and Solvents	75 1%	15 3%
E66 Control of Temp. and Humidity	95 2%	16 3%
E67 Monitored and Recorded Voltage Levels	96 2%	6 1%
E68 Adequate Fire Precautions	598 13%	69 14%
E69 Collection of Specimens	30*	-
E70 Sterilization	9*	5 1%
E71 Sterilization and Disinfection Techniques	100 2%	16 3%
E72 Disposable Items	12[illegible] 2%	24 5%
E73 Device Assuring Proper Sterilization	68 1%	17 3%
E74 Operation of Autoclave	139 3%	22 4%
E75 Examination and Reports	123 2%	22 4%
E76 Reference Specimens	3*	1*
E77 Specimen Records	168 3%	46 9%
E78 Data for Test Performed	337 7%	88 18%
E79 Records	87 1%	19 4%
E80 Copies/Records are Filed	81 1%	14 2%
E81 Terminology of Tissue Pathology Rpt	2*	1*
E82 Patient Receives Results by Written Consent	36*	4*
E83 Pertinent Normal Ranges Available	46 1%	18 3%
E84 List of Analytical Methods Maintained	86 1%	26 5%
E85 Outside Laboratory Notified and Meets Conditions	124 2%	28 5

* - Less than 1%

Chart No. 19 2(5)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION III	DE	PA	VA
Facility Total	4474	481	16	275	43
E63 Procedure Manual	1072 23%	94 19%	4 25%	23 8%	4 9%
E64 Facilities	109 2%	13 2%	2 12%	1*	-
E65 Proper Storage of Chemicals and Solvents	75 1%	22 4%	1 6%	-	1 2%
E66 Control of Temp. and Humidity	95 2%	10 2%	1 6%	2*	-
E67 Monitored and Recorded Voltage Levels	96 2%	-	-	-	-
E68 Adequate Fire Precautions	598 13%	61 12%	-	1*	2 4%
E69 Collection of Specimens	30*	1*	-	-	-
E70 Sterilization	9*	1*	-	1*	-
E71 Sterilization and Disinfection Techniques	100 2%	10 2%	-	4 1%	-
E72 Disposable Items	121 2%	9 1%	-	4 1%	-
E73 Device Assuring Proper Sterilization	68 1%	4*	-	-	
E74 Operation of Autoclave	139 3%	13 2%	-	4 1%	-
E75 Examination and Reports	123 2%	3*	-	1*	-
E76 Reference Specimens	3*	1*	-	1*	-
E77 Specimen Records	168 3%	6 1%	2 12%	3 1%	-
E78 Data for Test Performed	337 7%	19 3%	1 6%	3 1%	
E79 Records	87 1%	7 1%	1 6%	-	-
E80 Copies/Records are Filed	81 1%	1*	-	-	-
E81 Terminology of Tissue Pathology Reports	2*	1*	-	-	-
E82 Patient Receives Results by Written Request	36*	-	-	-	-
E83 Pertient Normal Ranges Available	46 1%	-	-	-	-
E84 List of Analytical Methods Maintained	86 1%	-	-	-	-
E85 Outside Laboratory Notified and Meets Conditions	124 2%	7 1%	-	2*	-

* - Less Than 1%

Chart No. 20 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION IV	FL	GA	TN
Facility Total	4474	646	226	81	79
E63 Procedure Manual	1072 23%	85 13%	29 12%	9 11%	2 2%
E64 Facilities	109 2%	6*	4 1%	-	-
E65 Proper Storage of Chemicals and Solvents	75 1%	3*	-	-	1 1%
E66 Control of Temp. and Humidity	95 2%	3*	2*	-	1 1%
E67 Monitored and Recorded Voltage Levels	96 2%	1*	-	-	1 1%
E68 Adequate Fire Precautions	598 13%	58 8%	23 10%	2 2%	10 12%
E69 Collection of Specimens	30*	-	-	-	-
E70 Sterilization	9*	1*	-	1 1%	-
E71 Sterilization and Disinfection Techniques	100 2%	13 2%	2*	-	-
E72 Disposable Items	121 2%	8 1%	3 1%	-	-
E73 Device Assuring Proper Sterilization	68 1%	2*	-	-	2 2%
E74 Operation of Autoclave	139 3%	6*	2*	-	1 1%
E75 Examination and Reports	123 2%	4*	1*	-	1 1%
E76 Reference Specimens	3*	-	-	-	-
E77 Specimen Records	168 3%	30 4%	6 2%	-	-
E78 Data for Test Performed	337 7%	35 5%	13 5%	4 4%	3 3%
E79 Records	87 1%	4*	2*	-	1 1%
E80 Copies/Records are Filed	81 1%	2*	-	-	-
E81 Terminology of Tissue Pathology Reports	2*	-	-	-	-
E82 Patient Receives Results by Written Request	36*	2*	-	-	1 1%
E83 Pertient Normal Ranges Available	46 1%	1*	-	-	-
E84 List of Analytical Methods Maintained	86 1%	2*	-	-	-
E85 Outside Laboratory Notified and Meets Conditions	124 2%	6*	1*	1 1%	1 1%

* - Less Than 1%

Chart No. 21 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION V	Mich.	Ohio
Facility Total	4474	581	131	141
E63 Procedure Manual	1072 23%	193 33%	44 33%	52 36%
E64 Facilities	109 2%	29 4%	15 11%	11 7%
E65 Proper Storage of Chemicals and Solvents	75 1%	7 1%	1*	3 2%
E66 Control of Temp. and Humidity	95 2%	20 3%	8 6%	5 3%
E67 Monitored and Recorded Voltage Levels	96 2%	3*	1*	2 1%
E68 Adequate Fire Precautions	598 13%	77 13%	33 25%	29 20%
E69 Collection of Specimens	30*	5*	-	-
E70 Sterilization	9*	1*	-	1*
E71 Sterilization and Disinfection Techniques	100 2%	20 3%	4 3%	4 2%
E72 Disposable Items	121 2%	28 4%	19 14%	3 2%
E73 Device Assuring Proper Sterilization	68 1%	8 1%	3 2%	-
E74 Operation of Autoclave	139 3%	18 3%	4 3%	6 4%
E75 Examination and Reports	123 2%	23 3%	3 2%	5 3%
E76 Reference Specimens	3*	1*	-	1*
E77 Specimen Records	168 3%	16 2%	5 3%	6 4%
E78 Data for Test Performed	337 7%	30 5%	1*	11 7%
E79 Records	87 1%	14 2%	6 4%	2 1%
E80 Copies/Records are Filed	81 1%	5*	1*	3 2%
E81 Terminology of Tissue Pathology Rpt	2*	-	-	-
E82 Patient Receives Results by Written Consent	36*	1*	-	-
E83 Pertinent Normal Ranges Available	46 1%	6 1%	1*	2 1%
E84 List of Analytical Methods Maintained	86 1%	8 1%	-	2 1%
E85 Outside Laboratory Notified and Meets Conditions	124 2%	10 1%	7 5%	3 2%

* - Less than 1%

Chart No. 22 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION VI	Ark.	New Mexico
Facility Total	4474	500	42	26
E63 Procedure Manual	1072 23%	106 21%	1 2%	9 34%
E64 Facilities	109 2%	4*	-	1 3%
E65 Proper Storage of Chemicals and Solvents	75 1%	9 1%	-	2 7%
E66 Control of Temp. and Humidity	95 2%	12 2%	-	-
E67 Monitored and Recorded Voltage Levels	96 2%	21 4%	4 9%	-
E68 Adequate Fire Precautions	598 13%	87 17%	9 21%	4 15%
E69 Collection of Specimens	30*	-	-	-
E70 Sterilization	9*	1*	-	-
E71 Sterilization and Disinfection Techniques	100 2%	26 5%	1 2%	-
E72 Disposable Items	121 2%	18 3%	-	-
E73 Device Assuring Proper Sterilization	68 1%	2*	-	-
E74 Operation of Autoclave	139 3%	22 4%	-	3 11%
E75 Examination and Reports	123 2%	32 6%	20 47%	2 7%
E76 Reference Specimens	3*	-	-	-
E77 Specimen Records	168 3%	15 3%	-	3 11%
E78 Data for Test Performed	337 7%	34 6%	-	4 15%
E79 Records	87 1%	21 4%	17 40%	1 3%
E80 Copies/Records are Filed	81 1%	26 5%	15 35%	4 15%
E81 Terminology of Tissue Pathology Rpt	2*	-	-	-
E82 Patient Receives Results by Written Consent	36*	22 4%	17 40%	2 7%
E83 Pertinent Normal Ranges Available	46 1%	6 1%	3 7%	-
E84 List of Analytical Methods Maintained	86 1%	9 1%	2 4%	-
E85 Outside Laboratory Notified and Meets Conditions	124 2%	16 3%	-	-

* - Less than 1%

Chart No. 23 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	4474	181	122	995
E63 Procedure Manual	1072 23%	26 14%	20 16%	227 22%
E64 Facilities	109 2%	2 1%	1*	14 1%
E65 Proper Storage of Chemicals and Solvents	75 1%	-	2 1%	3*
E66 Control of Temp. and Humidity	95 2%	-	1*	13 1%
E67 Monitored and Recorded Voltage Levels	96 2%	-	1*	53 5%
E68 Adequate Fire Precautions	598 13%	14 7%	17 13%	90 9%
E69 Collection of Specimens	30*	1*	-	21 2%
E70 Sterilization	9*	-	-	-
E71 Sterilization and Disinfection Techniques	100 2%	1*	1*	5*
E72 Disposable Items	121 2%	-	3 2%	16 1%
E73 Device Assuring Proper Sterilization	68 1%	2 1%	-	22 2%
E74 Operation of Autoclave	139 3%	5 2%	-	31 3%
E75 Examination and Reports	123 2%	3 1%	2 1%	7*
E76 Reference Specimens	3*	-	-	-
E77 Specimen Records	168 3%	4 2%	3 2%	32 3
E78 Data for Test Performed	337 7%	6 3%	7 5%	48 4%
E79 Records	87 1%	5 2%	1*	3*
E80 Copies/Records are Filed	81 1%	3 1%	1*	10 1%
E81 Terminology of Tissue Pathology Rpt	2*	-	-	-
E82 Patient Receives Results by Written Consent	36*	-	1*	4*
E83 Pertinent Normal Ranges Available	46 1%	-	-	3*
E84 List of Analytical Methods Maintained	86 1%	3 1%	1*	9*
E85 Outside Laboratory Notified and Meets Conditions	124 2%	6 3%	1*	29 2%

* - Less than 1%

Chart No. 24 2(b)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE CONDITION OF MANAGEMENT DURING THE MOST RECENT SURVEY

Deficiency	Nation	REGION X	AK
Facility Total	4474	155	7
E63 Procedure Manual	1072 23%	19 12%	-
E64 Facilities	109 2%	1*	-
E65 Proper Storage of Chemicals and Solvents	75 1%	1*	-
E66 Control of Temp. and Humidity	95 2%	2 1%	1 14%
E67 Monitored and Recorded Voltage Levels	96 2%	-	-
E68 Adequate Fire Precautions	598 13%	14 9%	1 14%
E69 Collection of Specimens	30*	-	-
E70 Sterilization	9*	-	-
E71 Sterilization and Disinfection Techniques	100 2%	-	-
E72 Disposable Items	121 2%	1*	1 14%
E73 Device Assuring Proper Sterilization	68 1%	3 1%	-
E74 Operation of Autoclave	139 3%	8 5%	-
E75 Examination and Reports	123 2%	-	-
E76 Reference Specimens	3*	-	-
E77 Specimen Records	168 3%	-	-
E78 Data for Test Performed	337 7%	3 1%	-
E79 Records	87 1%	-	-
E80 Copies/Records are Filed	81 1%	1*	1 14%
E81 Terminology of Tissue Pathology Rpt	2*	-	-
E82 Patient Receives Results by Written Consent	36*	-	-
E83 Pertinent Normal Ranges Available	46 1%	1*	-
E84 List of Analytical Methods Maintained	86 1%	2 1%	2 28%
E85 Outside Laboratory Notified and Meets Conditions	124 2%	-	-

* - Less than 1%

Chart No. 25 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Management (cross refers to the Independent Laboratory management condition)

REGION I

Deficiency	Nation	Region I	ME	NH
Facility Total	1443	16	6	1
E063 (A573) Procedure Manual	212 15%	1 6%	0	0
E064 (A574) Facilities	15 1%	0	0	0
E065 (A575) Proper Storage of Chemicals and solvents	5*	0	0	0
E066 (A576) Control of Temperature and Humidity	20 1%	0	0	0
E067 (A577) Monitored and Recorded Voltage Levels	3*	0	0	0
E068 (A578) Adequate Fire Precautions	65 5%	0	0	0
E069 (A579) Collection of Specimens	5*	0	0	0
E070 (A580) Sterilization	0	0	0	0
E071 (A581) Sterilization and Disinfection Techniques	19 1%	0	0	0
E072 (A582) Disposable Items	23 2%	0	0	0
E073 (A583) Device Assuring Proper sterilization	5*	0	0	0
E074 (A584) Operation of Auto clave	6*	0	0	0
E075 (A585) Examination and Reports	16 1%	0	0	0
E076 (A586) Reference Specimens	0	0	0	0
E077 (A587) Specimen Records	105 7%	1 6%	1 17%	0
E078 (A588) Data for Test Performed	65 5%	1 6%	0	0
E079 (A589) Records	18 1%	0	0	0
E080 (A590) Copies/Records are Filed	21 1%	0	0	0
E081 (A591) Terminology of Tissue Pathology Reports	1*	0	0	0
E082 (A592) Patient Receives Results by Written Consent	7*	0	0	0
E083 (A593) Pertinent Normal Ranges Available	22 2%	0	0	0
E084 (A594) List of Analytical Methods Maintained	16 1%	1 6%	0	0
E085 (A595) Outside Laboratory Notified and meets conditions	21 1%	0	0	0

* less than 1%

Chart No. 26 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Management (cross refers to the Independent Laboratory management condition)

REGION II

Deficiency		Nation	Region II
	Facility Total	1443	45
E063 (A573)	Procedure Manual	212 15%	0
E064 (A574)	Facilities	15 1%	0
E065 (A575)	Proper Storage of Chemicals and solvents	5*	0
E066 (A576)	Control of Temperature and Humidity	20 1%	0
E067 (A577)	Monitored and Recorded Voltage Levels	3*	0
E068 (A578)	Adequate Fire Precautions	65 5%	0
E069 (A579)	Collection of Specimens	5*	0
E070 (A580)	Sterilization	0	0
E071 (A581)	Sterilization and Disinfection Techniques	19 1%	0
E072 (A582)	Disposable Items	23 2%	0
E073 (A583)	Device Assuring Proper sterilization	5*	0
E074 (A584)	Operation of Auto clave	6*	0
E075 (A585)	Examination and Reports	16 1%	0
E076 (A586)	Reference Specimens	0	0
E077 (A587)	Specimen Records	105 7%	0
E078 (A588)	Data for Test Performed	65 5%	0
E079 (A589)	Records	18 1%	0
E080 (A590)	Copies/Records are Filed	21 1%	0
E081 (A591)	Terminology of Tissue Pathology Reports	1*	0
E082 (A592)	Patient Receives Results by Written Consent	7*	0
E083 (A593)	Pertinent Normal Ranges Available	22 2%	0
E084 (A594)	List of Analytical Methods Maintained	16 1%	0
E085 (A595)	Outside Laboratory Notified and meets conditions	21 1%	0

* less than 1%

Chart No. 27 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies
within the Hospital Laboratory Standard for Management
(cross refers to the Independent Laboratory management condition)

REGION III

Deficiency	Nation	Region III	DE	PA	VA
Facility Total	1443	43	0	14	6
E063 (A573) Procedure Manual	212 15%	0	0	0	0
E064 (A574) Facilities	15 1%	0	0	0	0
E065 (A575) Proper Storage of Chemicals and solvents	5*	0	0	0	0
E066 (A576) Control of Temperature and Humidity	20 1%	0	0	0	0
E067 (A577) Monitored and Recorded Voltage Levels	3*	0	0	0	0
E068 (A578) Adequate Fire Precautions	65 5%	2 5%	0	0	0
E069 (A579) Collection of Specimens	5*	1 2%	0	0	0
E070 (A580) Sterilization	0	0	0	0	0
E071 (A581) Sterilization and Disinfection Techniques	19 1%	0	0	0	0
E072 (A582) Disposable Items	23 2%	0	0	0	0
E073 (A583) Device Assuring Proper sterilization	5*	0	0	0	0
E074 (A584) Operation of Auto clave	6*	1 2%	0	0	0
E075 (A585) Examination and Reports	16 1%	1 2%	0	0	0
E076 (A586) Reference Specimens	0	0	0	0	0
E077 (A587) Specimen Records	105 7%	4 9%		0	0
E078 (A588) Data for Test Performed	65 5%	0	0	0	0
E079 (A589) Records	18 1%	0	0	0	0
E080 (A590) Copies/Records are Filed	21 1%	0	0	0	0
E081 (A591) Terminology of Tissue Pathology Reports	1*	0	0	0	0
E082 (A592) Patient Receives Results by Written Consent	7*	0	0	0	0
E083 (A593) Pertinent Normal Ranges Available	22 2%	0	0	0	0
E084 (A594) List of Analytical Methods Maintained	16 1%	0	0	0	0
E085 (A595) Outside Laboratory Notified and meets conditions	21 1%	0	0	0	0

* less than 1%

Chart No. 28 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies
within the Hospital Laboratory Standard for Management
(cross refers to the Independent Laboratory management condition)

REGION IV

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	1443	263	40	59	23
E063 Procedure Manual (A573)	212 15%	42 16%	1 3%	3 5%	0
E064 Facilities (A574)	15 1%	6 2%	0	1 2%	4 17%
E065 Proper Storage of (A575) Chemicals and solvents	5*	0	0	0	0
E066 Control of Temperature (A576) and Humidity	20 1%	7 3%	0	3 5%	0
E067 Monitored and Recorded (A577) Voltage Levels	3*	1*	0	0	1 4%
E068 Adequate Fire (A578) Precautions	65 5%	12 5%	1 3%	4 7%	2 9%
E069 Collection of Specimens (A579)	5*	2*	0	0	0
E070 Sterilization (A580)	0	0	0	0	0
E071 Sterilization and (A581) Disinfection Techniques	19 1%	1*	0	0	0
E072 Disposable Items (A582)	23 2%	2*	0	0	0
E073 Device Assuring Proper (A583) Sterilization	5*	0	0	0	0
E074 Operation of (A584) Auto clave	6*	0	0	0	0
E075 Examination and (A585) Reports	16 1%	1*	0	0	0
E076 Reference Specimens (A586)	0	0	0	0	0
E077 Specimen Records (A587)	105 7%	27 10%	4 10%	4 7%	1 4%
E078 Data for Test (A588) Performed	65 5%	17 6%	1 3%	7 12%	0
E079 Records (A589)	18 1%	4 2%	0	0	0
E080 Copies/Records (A590) are Filed	21 1%	11 4%	2 5%	2 3%	1 4%
E081 Terminology of (A591) Tissue Pathology Reports	1*	0	0	0	0
E082 Patient Receives (A592) Results by Written Consent	7*	0	0	0	0
E083 Pertinent Normal (A593) Ranges Available	22 2%	6 2%	0	0	0
E084 List of Analytical (A594) Methods Maintained	16 1%	4 2%	1 3%	0	0
E085 Outside Laboratory (A595) Notified and meets conditions	21 1%	1*	0	0	0

* less than 1%

Chart No. 29 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Management (cross refers to the Independent Laboratory management condition)

REGION V

Deficiency	Nation	Region V	MI	OH
Facility Total	1443	163	9	18
E063 (A573) Procedure Manual	212 15%	8 5%	0	0
E064 (A574) Facilities	15 1%	0	0	0
E065 (A575) Proper Storage of Chemicals and solvents	5*	0	0	0
E066 (A576) Control of Temperature and Humidity	20 1%	1*	0	0
E067 (A577) Monitored and Recorded Voltage Levels	3*	0	0	0
E068 (A578) Adequate Fire Precautions	65 5%	2 1%	0	0
E069 (A579) Collection of Specimens	5*	1*	0	0
E070 (A580) Sterilization	0	0	0	0
E071 (A581) Sterilization and Disinfection Techniques	19 1%	0	0	0
E072 (A582) Disposable Items	23 2%	0	0	0
E073 (A583) Device Assuring Proper sterilization	5*	0	0	0
E074 (A584) Operation of Auto clave	6*	0	0	0
E075 (A585) Examination and Reports	16 1%	0	0	0
E076 (A586) Reference Specimens	0	0	0	0
E077 (A587) Specimen Records	105 7%	7 4%		0
E078 (A588) Data for Test Performed	65 5%	4 2%	0	0
E079 (A589) Records	18 1%	0	0	0
E080 (A590) Copies/Records are Filed	21 1%	1*	0	0
E081 (A591) Terminology of Tissue Pathology Reports	1*	0	0	0
E082 (A592) Patient Receives Results by Written Consent	7*	0	0	0
E083 (A593) Pertinent Normal Ranges Available	22 2%	0	0	0
E084 (A594) List of Analytical Methods Maintained	16 1%	0	0	0
E085 (A595) Outside Laboratory Notified and meets conditions	21 1%	0	0	0

* less than 1%

Chart No. 30 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies
within the Hospital Laboratory Standard for Management
(cross refers to the Independent Laboratory management condition)

REGION VI

Deficiency	Nation	Region VI	AR	NH
Facility Total	1443	306	37	18
E063 Procedure Manual (A573)	212 15%	41 13%	4 11%	2 11%
E064 Facilities (A574)	15 1%	2*	0	0
E065 Proper Storage of (A575) Chemicals and solvents	5*	2*	0	0
E066 Control of Temperature (A576) and Humidity	20 1%	5 2%	0	0
E067 Monitored and Recorded (A577) Voltage Levels	3*	1*	1 3%	0
E068 Adequate Fire (A578) Precautions	65 5%	11 4%	1 3%	0
E069 Collection of Specimens (A579)	5*	0	0	0
E070 Sterilization (A580)	0	0	0	0
E071 Sterilization and (A581) Disinfection Techniques	19 1%	8 3%	0	0
E072 Disposable Items (A582)	23 2%	10 3%	0	0
E073 Device Assuring Proper (A583) sterilization	5*	1*	0	0
E074 Operation of (A584) Auto clave	6*	3 1%	0	0
E075 Examination and (A585) Reports	16 1%	7 2%	0	0
E076 Reference Specimens (A586)	0	0	0	0
E077 Specimen Records (A587)	105 7%	17 6%		0
E078 Data for Test (A588) Performed	65 5%	16 5%	0	1 6%
E079 Records (A589)	18 1%	11 4%	2 5%	0
E080 Copies/Records (A590) are Filed	21 1%	4 1%	2 5%	0
E081 Terminology of (A591) Tissue Pathology Reports	1*	0	0	0
E082 Patient Receives (A592) Results by Written Consent	7*	3 1%	0	0
E083 Pertinent Normal (A593) Ranges Available	22 2%	3 1%	0	0
E084 List of Analytical (A594) Methods Maintained	16 1%	1*	0	1 6%
E085 Outside Laboratory (A595) Notified and meets conditions	21 1%	5 2%	0	1 6%

* less than 1%

Chart No. 31 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Management (cross refers to the Independent Laboratory management condition)

REGION VII, VIII, IX

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	1443	232	183	92
E063 Procedure Manual (A573)	212 15%	68 29%	30 16%	0
E064 Facilities (A574)	15 1%	1*	3 2%	0
E065 Proper Storage of (A575) Chemicals and solvents	5*	2*	0	0
E066 Control of Temperature (A576) and Humidity	20 1%	2*	0	0
E067 Monitored and Recorded (A577) Voltage Levels	3*	1*	0	0
E068 Adequate Fire (A578) Precautions	65 5%	28 12%	6 3%	0
E069 Collection of Specimens (A579)	5*	0	1*	0
E070 Sterilization (A580)	0	0	0	0
E071 Sterilization and (A581) Disinfection Techniques	19 1%	7 3%	3 2%	0
E072 Disposable Items (A582)	23 2%	1*	10 5%	0
E073 Device Assuring Proper (A583) sterilization	5*	1*	3 2%	0
E074 Operation of (A584) Auto clave	6*	1*	1*	0
E075 Examination and (A585) Reports	16 1%	5 2%	2 1%	0
E076 Reference Specimens (A586)	0	0	0	0
E077 Specimen Records (A587)	105 7%	22 9%	21 11%	3 3%
E078 Data for Test (A588) Performed	65 5%	12 5%	9 5%	0
E079 Records (A589)	18 1%	2*	1*	0
E080 Copies/Records (A590) are Filed	21 1%	1*	2 1%	0
E081 Terminology of (A591) Tissue Pathology Reports	1*	0	1*	0
E082 Patient Receives (A592) Results by Written Consent	7*	4 2%	0	0
E083 Pertinent Normal (A593) Ranges Available	22 2%	9 4%	3 2%	0
E084 List of Analytical (A594) Methods Maintained	16 1%	5 2%	4 2%	0
E085 Outside Laboratory (A595) Notified and meets conditions	21 1%	13 6	2 1%	0

* less than 1%

Chart No. 32 2(b)2

Laboratories in Nonaccredited Hospitals with Deficiencies
within the Hospital Laboratory Standard for Management
(cross refers to the Independent Laboratory management condition)

REGION X

Deficiency	Nation	Region X	AK
Facility Total	1443	100	10
E063 Procedure Manual (A573)	212 15%	22 22%	1 10%
E064 Facilities (A574)	15 1%	3 3%	1 10%
E065 Proper Storage of (A575) Chemicals and solvents	5*	1 1%	0
E066 Control of Temperature (A576) and Humidity	20 1%	5 5%	1 10%
E067 Monitored and Recorded (A577) Voltage Levels	3*	0	0
E068 Adequate Fire (A578) Precautions	65 5%	4 4%	0
E069 Collection of Specimens (A579)	5*	0	0
E070 Sterilization (A580)	0	0	0
E071 Sterilization and (A581) Disinfection Techniques	19 1%	0	0
E072 Disposable Items (A582)	23 2%	0	0
E073 Device Assuring Proper (A583) sterilization	5*	0	0
E074 Operation of (A584) Auto clave	6*	0	0
E075 Examination and (A585) Reports	16 1%	0	0
E076 Reference Specimens (A586)	0	0	0
E077 Specimen Records (A587)	105 7%	3 3%	
E078 Data for Test (A588) Performed	65 5%	6 6%	1 10%
E079 Records (A589)	18 1%	0	0
E080 Copies/Records (A590) are Filed	21 1%	2 2%	1 10%
E081 Terminology of (A591) Tissue Pathology Reports	1*	0	0
E082 Patient Receives (A592) Results by Written Consent	7*	0	0
E083 Pertinent Normal (A593) Ranges Available	22 2%	1 1%	0
E084 List of Analytical (A594) Methods Maintained	16 1%	1 1%	0
E085 Outside Laboratory (A595) Notified and meets conditions	21 1%	0	0

* less than 1%

Please list for each standard and factor within the quality control condition the number and per cent of labs which did not meet that specific standard and factor (frequency and per cent for each code E87-E95).

2(c) A Chart 33 lists the number and percentage of independent laboratories which were cited with standard and factor level deficiencies within the quality control condition, 405.1317 (E87-E95). The chart also includes the number of nonaccredited hospital laboratories which were cited with deficiencies under 482.27(f) which is a standard under the hospital laboratory regulations that cross refers to the independent laboratory quality control condition (405.1317).

Deficiency data for Medicare only independent laboratories and Medicare independent/CLIA laboratories are included in the numbers under the independent laboratory category on charts 33 through 40. These numbers do not reflect deficiency data for CLIA only laboratories because MMACS is not programmed to capture data for CLIA only labs (of which there are 197), or deficiency data on accredited hospital laboratories. Accredited facilities are not routinely surveyed by our State survey agencies and we do not routinely receive survey data from the accreditation organizations.

Charts 34 through 48 list the number and percentage of laboratories which did not meet specific standards and factors within the independent laboratory condition of quality control during the most recent survey.

(d) Q Looking at each specialty methodology (microbiology, serology, chemistry, immunohematology, hematology, exfoliative cytology/histo- and oral pathology, and radiobioassay) (1) how many and (2) what per cent of labs did not meet the quality control requirements for that particular specialty? (frequency and percent for each code: E114, E122, E126, E148, E163, E193, E198 , E208, E252, E272, E285, E286, E294)

(d) A Charts 49 through 64 list the number and percentage of independent laboratories and non-accredited hospital laboratories which did not meet the quality control requirements for the specialties of bacteriology (E114) parasitology (E122) virology (E126), syphilis serology (E148), non-syphilis serology (E163), chemistry (E193), urinalysis (E198) immunohematology (E208), hematology (E252), cytology (E273), histopathology (E185), oral pathology (E286) and radiobioassay (E294) during the most current survey.

These charts reflect deficiency data on Medicare only independent laboratories, Medicare independent/CLIA laboratories and non-accredited hospital laboratories because MMACS is not programmed to capture data for CLIA only laboratories and accredited hospitals. Accredited hospitals are not routinely surveyed by our State survey agencies and we do not routinely receive survey data from the accreditation organizations.

(e) Q For all labs in question #1, above, list the 15 most common deficiencies cited in the state inspections for the most recent year by region and nationally. Also, please indicate the number and per cent of labs for which the deficiency was reported. (If a lab had more than one deficiency, count each deficiency separately; so a lab with three deficiencies would be counted three times.)

(e) A Charts 65 through 82 list the frequency and percentage of the fifteen most common deficiencies cited in independent laboratories and nonaccredited hospital laboratories during the State inspections for the most recent year for each subcommittee member's state, each region and nationally.

These charts reflect deficiency data on Medicare only independent laboratories, Medicare independent/CLIA laboratories and nonaccredited hospital laboratories because MMACS is not programmed to capture data for CLIA only laboratories and accredited hospitals. Accredited hospitals are not routinely surveyed by our state survey agencies and we do not routinely receive survey data from the accreditation organizations.

LABORATORIES WITH STANDARD AND/OR FACTOR LEVEL DEFICIENCIES
WITHIN THE QUALITY CONTROL CONDITION (405.1317) CITED DURING THE MOST CURRENT SURVEY (E87-95)

Chart No. 33

	No Standard or Factor Level Deficiencies		At least One Standard or Factor Level Deficiency		Three or More Standard or Factor Level Deficiencies	
	Independent Labs.	Non-accredited Hospital Labs.	Independent Labs.	Non-accredited Hospital Labs.	Independent Labs.	Non-accredited Hospital Labs.
National	638 36%	905 62%	2894 64%	554 38%	830 18%	217 15%
Region I	86 25%	24 92%	259 75%	2 8%	124 36%	0
ME	0	5 83%	7 100%	1 17%	2 28%	0
NH	3 20%	1 100%	12 80%	0	4 27%	0
Region II	136 28%	45 100%	343 72%	0	112 23%	0
Region III	204 42%	33 75%	284 58%	11 25%	100 21%	7 16%
DE	5 29%	0	12 71%	0	0	0
PA	152 55%	13 93%	124 45%	1 7%	27 10%	0
VA	23 50%	5 83%	23 50%	1 17%	4 9%	1 17%
Region IV	262 40%	113 43%	396 60%	149 57%	113 [illegible]	62 24%
FLA	84 37%	27 66%	146 63%	14 34%	42 18%	6 15%
GA	44 53%	17 29%	39 47%	42 71%	11 13%	18 31%
TN	28 35%	9 39%	51 65%	14 61%	15 19%	6 26%
Region V	238 41%	144 89%	347 59%	17 11%	77 13%	7 4%
MI	48 37%	11 100%	83 63%	0	20 15%	0
OH	57 40%	17 94%	85 60%	1 6%	11 8%	0
Region VI	166 32%	208 68%	349 68%	100 32%	109 21%	36 12%
AR	35 85%	28 74%	6 15%	10 26%	0	0
NM	4 15%	11 61%	22 85%	7 39%	5 19%	2 11%
Region VII	97 55%	95 40%	81 45%	140 60%	11 6%	58 25%
Region VIII	45 36%	109 58%	79 64%	79 42%	22 18%	32 17%
Region IX	321 32%	90 98%	679 68%	2 2%	156 16%	1 1%
Region X	81 51%	44 45%	77 49%	54 55%	6 4%	14 14%
AK	4 57%	1 10%	3 43%	9 90%	0	3 30%

Chart No. 34 2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE
QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region I	ME	NH
Facility Total	4474	346	8	
E87 Quality Control - General	88 1%	6 1%	-	-
E88 Maintenance, Inspection and Testing	1437 32%	140 40%	5 62%	10 66%
E89 Monitoring Temperature Controlled Spaces	695 15%	107 30%	4 50%	3 20%
E90 Labeling of Reagents and Solutions	649 14%	106 30%	2 25%	3 20%
E91 Availability of Current Manuals	1134 25%	110 31%	7 87%	5 33%
E93 Maintenance and Availability of Records	674 15%	100 28%	3 37%	5 33%
E94 Adequate Stability of Transported Specimens	128 2%	10 2%	2 25%	-
E95 Methodologies	129 2%	16 4%	-	2 13%

Chart No. 35 2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region II	Region III
Facility Total	4474	467	481
E87 Quality Control - General	88 1%	22 4%	7 1%
E88 Maintenance, Inspection and Testing	1437 32%	200 42%	129 26%
E89 Monitoring Temperature Controlled Spaces	695 15%	80 17%	68 14%
E90 Labeling of Reagents and Solutions	649 14%	120 25%	62 12%
E91 Availability of Current Manuals	1134 25%	119 25%	119 24%
E93 Maintenance and Availability of Records	674 15%	51 10%	88 18%
E94 Adequate Stability of Transported Specimens	128 2%	25 5%	8 1%
E95 Methodologies	129 2%	33 7%	10 2%

Chart No. 36 2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE
QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	4474	467	226	81	79
E87 Quality Control - General	88 1%	5*	1*	1 1%	-
E88 Maintenance, Inspection and Testing	1437 32%	153 23%	72 31%	24 29%	16 20%
E89 Monitoring Temperature Controlled Spaces	695 15%	63 9%	28 12%	12 14%	6 7%
E90 Labeling of Reagents and Solutions	649 14%	37 5%	21 9%	3 3%	7 8%
E91 Availability of Current Manuals	1134 25%	168 26%	57 25%	16 19%	18 22%
E93 Maintenance and Availability of Records	674 15%	161 24%	59 26%	15 18%	21 26%
E94 Adequate Stability of Transported Specimens	128 2%	18 2%	3 1%	1 1%	1 1%
E95 Methodologies	129 2%	7 1%	3 1%	1 1%	-

* - Less Than 1%.

Chart No. 37

2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region VI	AR	NM
Facility Total	4474	500	42	26
E87 Quality Control - General	88 1%	8 1%	1 2%	-
E88 Maintenance, Inspection and Testing	1437 32%	161 32%	2 4%	4 15%
E89 Monitoring Temperature Controlled Spaces	695 15%	103 20%	-	6 23%
E90 Labeling of Reagents and Solutions	649 14%	73 14%	2 4%	8 30%
E91 Availability of Current Manuals	1134 25%	187 37%	-	11 42%
E93 Maintenance and Availability of Records	674 15%	72 14%	-	12 46%
E94 Adequate Stability of Transported Specimens	128 2%	12 2%	-	2 7%
E95 Methodologies	129 2%	24 4%	1 2%	-

Chart No. 38

2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region V	MI	OH
Facility Total	4474	581	131	141
E87 Quality Control - General	88 1%	22 3%	4 3%	7 4%
E88 Maintenance, Inspection and Testing	1437 32%	185 31%	41 31%	41 29%
E89 Monitoring Temperature Controlled Spaces	695 15%	97 16%	36 27%	20 14%
E90 Labeling of Reagents and Solutions	649 14%	85 14%	36 27%	16 11%
E91 Availability of Current Manuals	1134 25%	79 13%	12 9%	15 10%
E93 Maintenance and Availability of Records	674 15%	96 16%	12 9%	23 16%
E94 Adequate Stability of Transported Specimens	128 2%	12 2%	4 3%	3 2%
E95 Methodologies	129 2%	17 2%	2 1%	7 4%

Chart No. 39 2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	4474	181	122	995
E87 Quality Control - General	88 1%	-	1*	16 1%
E88 Maintenance, Inspection and Testing	1437 32%	24 13%	32 26%	384 38%
E89 Monitoring Temperature Controlled Spaces	695 15%	30 16%	16 13%	112 11%
E90 Labeling of Reagents and Solutions	649 14%	5 2%	16 13%	133 13%
E91 Availability of Current Manuals	1134 25%	23 12%	25 20%	297 29%
E93 Maintenance and Availability of Records	674 15%	15 8%	31 25%	39 3%
E94 Adequate Stability of Transported Specimens	128 2%	4 2%	3 2%	35 3%
E95 Methodologies	129 2%	3 1%	5 4%	13 1%

Chart No. 40 2(c)(2)

INDEPENDENT LABORATORIES CITED WITH DEFICIENCIES WITHIN THE QUALITY CONTROL CONDITION OF THE MOST RECENT SURVEY

Deficiency	Nation	Region X	Alaska
Facility Total	4474	155	7
E87 Quality Control - General	88 1%	1*	-
E88 Maintenance, Inspection and Testing	1437 32%	29 18%	-
E89 Monitoring Temperature Controlled Spaces	695 15%	19 12%	-
E90 Labeling of Reagents and Solutions	649 14%	12 7%	-
E91 Availability of Current Manuals	1134 25%	7 4%	1 14%
E93 Maintenance and Availability of Records	674 15%	21 13%	3 42%
E94 Adequate Stability of Transported Specimens	128 2%	1*	-
E95 Methodologies	129 2%	1*	-

* - Less Than 1%.

Chart No 41 2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION I

Deficiency		Nation	Region I	ME	NH
	Facility Total	1443	16	6	1
E087 Quality Control-General (A596)		25 2%	0	0	0
E088 Maintenance, Inspection (A597) and Testing		343 24%	1 6%	0	0
E089 Monitoring Temperature (A598) Controlled Spaces		217 15%	0	0	0
E090 Labeling of Reagents (A599) and Solutions		134 9%	0	0	0
E091 Availability of Current (A600) Manuals		286 20%	2 13%	1 17%	0
E093 ~~Maintenance and~~ (A602) Availability of Records		304 21%	1 6%	1 17%	0
E094 Adequate Stability of (A603) Transported Specimens		37 3%	0	0	0
E095 (A604) Methodologies		47 3%	0	0	0

Chart No. 42 2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION II

Deficiency	Nation	Region II
Facility Total	1443	45
E087 (A596) Quality Control-General	25 2%	0
E088 (A597) Maintenance, Inspection and Testing	343 24%	0
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	0
E090 (A599) Labeling of Reagents and Solutions	134 9%	0
E091 (A600) Availability of Current Manuals	286 20%	0
E093 (A602) Maintenance and Availability of Records	304 21%	0
E094 (A603) Adequate Stability of Transported Specimens	37 3%	0
E095 (A604) Methodologies	47 3%	0

Chart No. 43 2(c)2

Laboratories in Nonaccredited Hospitals
with Deficiencies within the Hospital
Laboratory Standard for Quality Control
(which cross refers to Independent Laboratory
Quality Control Condition)

REGION III

Deficiency	Nation	Region III	DE	PA	VA
Facility Totals	1443	43	0	14	6
E087 Quality Control-General (A596)	25 2%	0	0	0	0
E088 Maintenance, Inspection (A597) and Testing	343 24%	5 12%	0	1 7%	1 17%
E089 Monitoring Temperature (A598) Controlled Spaces	217 15%	8 19%	0	0	0
E090 Labeling of Reagents (A599) and Solutions	134 9%	9 21%	0	0	0
E091 Availability of Current (A600) Manuals	286 20%	12 28%	0	0	1 17%
E093 Maintenance and (A602) Availability of Records	304 21%	14 33%	0	0	1 17%
E094 Adequate Stability of (A603) Transported Specimens	37 3%	0	0	0	0
E095 (A604) Methodologies	47 3%	0	0	0	0

Chart No. 44

2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION IV

Deficiency	Nation	Region IV	FL	GA	TN
Facility Totals	1443	263	40	59	23
E087 (A596) Quality Control-General	25 2%	5 2%	0	1 2%	0
E088 (A597) Maintenance, Inspection and Testing	343 24%	80 30%	4 10%	26 44%	8 35%
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	31 12%	3 8%	8 14%	4 17%
E090 (A599) Labeling of Reagents And Solutions	134 9%	15 6%	2 5%	0	5 22%
E091 (A600) Availability of Current Manuals	286 20%	87 33%	12 30%	26 44%	5 22%
E093 (A602) Maintenance and Availability of Records	304 21%	100 38%	11 28%	24 41%	10 43%
E094 (A603) Adequate Stability of Transported Specimens	37 3%	20 8%	0	6 10%	0
E095 (A604) Methodologies	47 3%	14 5%	0	7 12%	0

Chart No. 45 2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION V

Deficiency	Nation	Region V	MI	OH
Facility Totals	1443	163	9	18
E087 (A596) Quality Control-General	25 2%	2 1%	0	0
E088 (A597) Maintenance, Inspection And Testing	343 24%	11 7%	0	0
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	4 2%	0	0
E090 (A599) Labeling of Reagents And Solutions	134 9%	7 4%	0	0
E091 (A600) Availability of Current Manuals	286 20%	11 7%	0	3 17%
E093 (A602) Maintenance and Availability of Records	304 21%	13 8%	0	1 6%
E094 (A603) Adequate Stability of Transported Specimens	37 3%	0	0	0
E095 (A604) Methodologies	47 3%	4 2%	0	3 17%

Chart No. 46 2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION VI

Deficiency		Nation	Region VI	AR	NH
	Facility Total	1443	306	37	18
E087 (A596)	Quality Control-General	25 2%	5 2%	0	0
E088 (A597)	Maintenance, Inspection And Testing	343 24%	66 22%	2 5%	2 11%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	36 12%	1 3%	2 11%
E090 (A599)	Labeling of Reagents And Solutions	134 9%	33 11%	2 5%	5 28%
E091 (A600)	Availability of Current Manuals	286 20%	62 20%	3 8%	6 33%
E093 (A602)	Maintenance and Availability of Records	304 21%	38 12%	1 3%	3 17%
E094 (A603)	Adequate Stability of Transported Specimens	37 3%	5 2%	1 3%	0
E095 (A604)	Methodologies	47 3%	11 4%	3 8%	0

Chart No. 47 2(c)2

Laboratories in Nonaccredited Hospitals
with Deficiencies within the Hospital
Laboratory Standard for Quality Control
(which cross refers to Independent Laboratory
Quality Control Condition)

REGION VII, VIII & IX

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	1443	232	183	92
E087 (A596) Quality Control-General	25 2%	2 1%	5 3%	2 2%
E088 (A597) Maintenance, Inspection and Testing	343 24%	98 42%	64 35%	0
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	80 34%	32 17%	6 7%
E090 (A599) Labeling of Reagents and Solutions	134 9%	32 14%	17 9%	4 4%
E091 (A600) Availability of Current Manuals	286 20%	61 26%	32 17%	3 3%
E093 (A602) Maintenance and Availability of Records	304 21%	51 22%	52 28%	1 1%
E094 (A603) Adequate Stability of Transported Specimens	37 3%	2 1%	7 4%	2 2%
E095 (A604) Methodologies	47 3%	3 1%	10 5%	1 1%

Chart No. 48

2(c)2

Laboratories in Nonaccredited Hospitals with Deficiencies within the Hospital Laboratory Standard for Quality Control (which cross refers to Independent Laboratory Quality Control Condition)

REGION X

Deficiency		Nation	Region X	AK
	Facility Total	1443	100	10
E087 (A596)	Quality Control-General	25 2%	4 4%	0
E088 (A597)	Maintenance, Inspection And Testing	343 24%	18 18%	1 10%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	20 20%	0
E090 (A599)	Labeling of Reagents And Solutions	134 9%	17 17%	1 10%
E091 (A600)	Availability of Current Manuals	286 20%	16 16%	6 60%
E093 (A602)	Maintenance and Availability of Records	304 21%	34 34%	8 80%
E094 (A603)	Adequate Stability of Transported Specimens	37 3%	1 1%	0
E095 (A604)	Methodologies	47 3%	4 4%	1 10%

Chart No. 49 2(d)

Independent Laboratories which did not meet the quality
Control requirements for (sub)Specialties during the most current survey

Region I

Deficiency	Nation	Region I	ME	NH
Facility Total	4474	346	8	15
E114 (1) Bacteriology and Mycology	75 1%	5 1%	5 1%	—
E122 Parasitology	5*	5 1%	—	—
E126 (2) Virology	6*	—	—	—
E148 Syphilis Serology	32*	—	—	—
E163 Non-syphilis Serology	29*	—	—	—
E193 Clinical Chemistry	98 2%	5 1%	—	1 6%
E198 Urinalysis	47 1%	5 1%	—	—
E208 Immunohematolgy	36*	—	—	—
E252 Hematology	43*	—	—	—
E272 (1) Enfoliative Cytology	3*	—	—	—
E285 (2) Histopathology	1*	—	—	—
E286 Oral Pathology	0	—	—	—
E294 Radiobioassay	0	—	—	—

* less than 1%

Chart No. 5C 2(d)

. Independent Laboratories which did not meet the quality Control requirements for (sub)Specialties during the most current survey

Region II

Deficiency	Nation	Region II
Facility Total	4474	467
E114 (1) Bacteriology and Mycology	75 1%	10 8%
E122 Parasitology	5*	—
E126 (2) Virology	6*	3 2%
E148 Syphilis Serology	32*	9 8%
E163 Non-syphilis Serology	29*	6 5%
E193 Clinical Chemistry	98 2%	23 20%
E198 Urinalysis	47 1%	14 12%
E208 Immunohematolgy	36*	3 2%
E252 Hematology	43*	5 4%
E272 (1) Enfoliative Cytology	3*	—
E285 (2) Histopathology	1*	—
E286 Oral Pathology	0	—
E294 Radiobioassay	0	—

* less than 1%

Chart No. 51 2(d)

Independent Laboratories which did not meet the quality
Control requirements for (sub)Specialties during the most current survey

Region III

Deficiency	Nation	Region III	DE	PA	VA
Facility Total	4474	481	16	275	43
E114 (1) Bacteriology and Mycology	75 1%	—	—	—	—
E122 Parasitology	5*	—	—	—	—
E126 (2) Virology	6*	—	—	—	—
E148 Syphilis Serology	32*	—	—	—	—
E163 Non-syphilis Serology	29*	—	—	—	—
E193 Clinical Chemistry	98 2%	—	—	—	—
E198 Urinalysis	47 1%	—	—	—	—
E208 Immunohematolgy	36*	—	—	—	—
E252 Hematology	43*	—	—	—	—
E272 (1) Enfoliative Cytology	3*	—	—	—	—
E285 (2) Histopathology	1*	—	—	—	—
E286 Oral Pathology	0	—	—	—	—
E294 Radiobioassay	0	—	—	—	—

* less than 1%

Chart No. 52 2(a)

Independent Laboratories which did not meet the quality
Control requirements for (sub)Specialties during the most current survey

Region IV

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	4474	646	226	81	79
E114 (1) Bacteriology and Mycology	75 1%	—	—	—	—
E122 Parasitology	5*	—	—	—	—
E126 (2) Virology	6*	—	—	—	—
E148 Syphilis Serology	32*	—	—	—	—
E163 Non-syphilis Serology	29*	—	—	—	—
E193 Clinical Chemistry	98 2%	9 1%	—	3 1%	—
E198 Urinalysis	47 1%	5 1%	—	3 1%	—
E208 Immunohematolgy	36*	—	—	—	—
E252 Hematology	43*	—	—	—	—
E272 (1) Enfoliative Cytology	3*	—	—	—	—
E285 (2) Histopathology	1*	—	—	—	—
E286 Oral Pathology	0	—	—	—	—
E294 Radiobioassay	0	—	—	—	—

* less than 1%

Chart No. 53

2(a)

Independent Laboratories which did not meet the quality Control requirements for (sub)Specialties during the most current survey

Region V

Deficiency	Nation	Region V	MI	OH
Facility Total	4474	581	131	141
E114 (1) Bacteriology and Mycology	75 1%	19 3%	4 3%	5 3%
E122 Parasitology	5*	—	—	—
E126 (2) Virology	6*	—	—	—
E148 Syphilis Serology	32*	7 1%	—	—
E163 Non-syphilis Serology	29*	—	—	3 2%
E193 Clinical Chemistry	98 2%	16 2%	2 1%	8 5%
E198 Urinalysis	47 1%	—	—	—
E208 Immunohematolgy	36*	6 1%	2 1%	—
E252 Hematology	43*	11 1%	—	5 3%
E272 (1) Enfoliative Cytology	3*	—	—	—
E285 (2) Histopathology	1*	—	—	—
E286 Oral Pathology	0	—	—	—
E294 Radiobioassay	0	—	—	—

* less than 1%

Chart No. 54 2(d)

Independent Laboratories which did not meet the quality Control requirements for (sub)Specialties during the most current survey

Region VI

Deficiency	Nation	Region VI	AR	NM
Facility Total	4474	500	42	26
E114 (1) Bacteriology and Mycology	75 1%	—	—	1 3%
E122 Parasitology	5*	—	—	—
E126 (2) Virology	6*	—	—	—
E148 Syphilis Serology	32*	—	—	—
E163 Non-syphilis Serology	29*	—	—	—
E193 Clinical Chemistry	98 2%	7 1%	—	—
E198 Urinalysis	47 1%	—	—	—
E208 Immunohematolgy	36*	—	—	—
E252 Hematology	43*	—	—	—
E272 (1) Enfoliative Cytology	3*	—	—	—
E285 (2) Histopathology	1*	—	—	—
E286 Oral Pathology	0	—	—	—
E294 Radiobioassay	0	—	—	—

* less than 1%

Chart No. 55 2(d)

Independent Laboratories which did not meet the quality
Control requirements for (sub)Specialties during the most current survey

Region VII, VIII, IX

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	4474	181	122	995
E114 (1) Bacteriology and Mycology	75 1%	2 1%	2 1%	19 1%
E122 Parasitology	5*	—	—	—
E126 (2) Virology	6*	—	—	—
E148 Syphilis Serology	32*	—	2 1%	10 1%
E163 Non-syphilis Serology	29*	—	—	11 1%
E193 Clinical Chemistry	98 2%	2 1%	—	—
E198 Urinalysis	47 1%	2 1%	2 1%	10 1%
E208 Immunohematolgy	36*	—	—	17 1%
E252 Hematology	43*	—	—	—
E272 (1) Enfoliative Cytology	3*	—	—	—
E285 (2) Histopathology	1*	—	—	—
E286 Oral Pathology	0	—	—	—
E294 Radiobioassay	0	—	—	—

* less than 1%

Chart No. 56 2(d)

Independent Laboratories which did not meet the quality Control requirements for (sub)Specialties during the most current survey

Region X

Deficiency	Nation	Region X	AK
Facility Total	4474	155	
E114 (1) Bacteriology and Mycology	75 1%	—	—
E122 Parasitology	5*	—	—
E126 (2) Virology	6*	—	—
E148 Syphilis Serology	32*	—	—
E163 Non-syphilis Serology	29*	—	—
E193 Clinical Chemistry	98 2%	—	—
E198 Urinalysis	47 1%	—	—
E208 Immunohematolgy	36*	—	—
E252 Hematology	43*	—	—
E272 (1) Enfoliative Cytology	3*	—	—
E285 (2) Histopathology	1*	—	—
E286 Oral Pathology	0	—	—
E294 Radiobioassay	0	—	—

* less than 1%

Chart No. 57 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region I	ME	NH
Facility Total	1443	16	6	1
E114 Bacteriology and Mycology (A623)	20 1%	—	—	—
E122 Parasitology (A631)	2*	—	—	—
E126 Virology (A635)	—	—	—	—
E148 Syphilis Serology (A657)	3*	—	—	—
E163 Non-syphilis Serology (A672)	5*	—	—	—
E193 Clinical Chemistry (A702)	17 1%	—	—	—
E198 Urinalysis (A707)	9 1%	—	—	—
E208 Immunohematology (A717)	4*	—	—	—
E252 Hematology (A761)	9 1%	—	—	—
E272 Exfoliative Cytology (A781)	—	—	—	—
E285 Histopathology (A794)	—	—	—	—
E286 Oral Pathology (A795)	—	—	—	—
E294 Radiobioassay (A803)	—	—	—	—

* - Less Than 1%.

Chart No. 58 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency		Nation	Region II
	Facility Total	1443	45
E114 (A623)	Bacteriology and Mycology	20 1%	—
E122 (A631)	Parasitology	2*	—
E126 (A635)	Virology	—	—
E148 (A657)	Syphilis Serology	3*	—
E163 (A672)	Non-syphilis Serology	5*	—
E193 (A702)	Clinical Chemistry	17 1%	—
E198 (A707)	Urinalysis	9 1%	—
E208 (A717)	Immunohematology	4*	—
E252 (A761)	Hematology	9 1%	—
E272 (A781)	Exfoliative Cytology	—	—
E285 (A794)	Histopathology	—	—
E286 (A795)	Oral Pathology	—	—
E294 (A803)	Radiobioassay	—	—

* Less Than 1%

Chart No. 59 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region III	DE	PA	VA
Facility Total	1443	43	0	14	6
E114 Bacteriology and Mycology (A623)	20 1%	—	—	—	—
E122 Parasitology (A631)	2*	—	—	—	—
E126 Virology (A635)	—	—	—	—	—
E148 Syphilis Serology (A657)	3*	—	—	—	—
E163 Non-syphilis Serology (A672)	5*	—	—	—	—
E193 Clinical Chemistry (A702)	17 1%	—	—	—	—
E198 Urinalysis (A707)	9 1%	—	—	—	—
E208 Immunohematology (A717)	4*	—	—	—	—
E252 Hematology (A761)	9 1%	—	—	—	—
E272 Exfoliative Cytology (781)	—	—	—	—	—
E285 Histopathology (A794)	—	—	—	—	—
E286 Oral Pathology (A795)	—	—	—	—	—
E294 Radiobioassay (A803)	—	—	—	—	—

* less Than 1%

Chart No. 60 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	1443	263	40	59	23
E114 Bacteriology and Mycology (A623)	20 1%	3 1%	—	—	—
E122 Parasitology (A631)	2*	—	—	—	—
E126 Virology (A635)	—	—	—	—	—
E148 Syphilis Serology (A657)	3*	—	—	—	—
E163 Non-syphilis Serology (A672)	5*	1*	—	1 2%	—
E193 Clinical Chemistry (A702)	17 1%	6 2%	—	2 3%	—
E198 Urinalysis (A707)	9 1%	—	—	—	—
E208 Immunohematology (A717)	4*	—	—	—	—
E252 Hematology (A761)	9 1%	2 1%	—	—	—
E272 Exfoliative Cytology (781)	—	—	—	—	—
E285 Histopathology (A794)	—	—	—	—	—
E286 Oral Pathology (A795)	—	—	—	—	—
E294 Radiobioassay (A803)	—	—	—	—	—

* less Than 1%

Chart No. 61 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency		Nation	Region V	Mich	Ohio
	Facility Total	1443	163	9	18
E114 (A623)	Bacteriology and Mycology	20 1%	2 1%	—	1 6%
E122 (A631)	Parasitology	2*	1 1%	—	1 6%
E126 (A635)	Virology	—	—	—	—
E148 (A657)	Syphilis Serology	3*	—	—	—
E163 (A672)	Non-syphilis Serology	5*	—	—	—
E193 (A702)	Clinical Chemistry	17 1%	—	—	—
E198 (A707)	Urinalysis	9 1%	—	—	—
E208 (A717)	Immunohematology	4*	2 1%	—	—
E252 (A761)	Hematology	9 1%	—	—	—
E272 (A781)	Exfoliative Cytology	—	—	—	—
E285 (A794)	Histopathology	—	—	—	—
E286 (A795)	Oral Pathology	—	—	—	—
E294 (A803)	Radiobioassay	—	—	—	—

* - Less Than 1%.

Chart No. 62 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region VI	Ark	New Mexico
Facility Total	1443	306	37	18
E114 Bacteriology and Mycology (A623)	20 1%	6 2%	—	1 6%
E122 Parasitology (A631)	2*	—	—	—
E126 Virology (A635)	—	—	—	—
E148 Syphilis Serology (A657)	3*	2 1%	—	—
E163 Non-syphilis Serology (A672)	5*	2 1%	—	—
E193 Clinical Chemistry (A702)	17 1%	4 1%	—	1 6%
E198 Urinalysis (A707)	9 1%	3 1%	—	—
E208 Immunohematology (A717)	4*	2 1%	—	—
E252 Hematology (A761)	9 1%	3 1%	—	—
E272 Exfoliative (A781) Cytology	—	—	—	—
E285 Histopathology (A794)	—	—	—	—
E286 Oral Pathology (A795)	—	—	—	—
E294 Radiobioassay (A803)	—	—	—	—

* - Less Than 1%.

Chart No. 63 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	1443	232	183	92
E114 Bacteriology and Mycology (A623)	20 1%	2 1%	2 1%	1 1%
E122 Parasitology (A631)	2*	—	1 1%	—
E126 Virology (A635)	—	—	—	—
E148 Syphilis Serology (A657)	3*	—	1 1%	—
E163 Non-syphilis Serology (A672)	5*	2 1%	—	—
E193 Clinical Chemistry (A702)	17 1%	1*	4 2%	1 1%
E198 Urinalysis (A707)	9 1%	4 2%	—	2 2%
E208 Immunohematology (A717)	4*	—	—	—
E252 Hematology (A761)	9 1%	1*	2 1%	—
E272 Exfoliative (A781) Cytology	—	—	—	—
E285 Histopathology (A794)	—	—	—	—
E286 Oral Pathology (A795)	—	—	—	—
E294 Radiobioassay (A803)	—	—	—	—

* - Less Than 1%.

Chart No. 64 2(d)

LABORATORIES IN NONACCREDITED HOSPITALS WHICH DID NOT MEET THE QUALITY CONTROL REQUIREMENTS FOR (SUB)SPECIALTIES DURING THE MOST CURRENT SURVEY

Deficiency	Nation	Region X	AK
Facility Total	1443	100	10
E114 Bacteriology and Mycology (A623)	20 1%	4 4%	1 10%
E122 Parasitology (A631)	2*	—	—
E126 Virology (A635)	—	—	—
E148 Syphilis Serology (A657)	3*	—	—
E163 Non-syphilis Serology (A672)	5*	—	—
E193 Clinical Chemistry (A702)	17 1%	1 1%	—
E198 Urinalysis (A707)	9 1%	—	—
E208 Immunohematology (A717)	4*	—	—
E252 Hematology (A761)	9 1%	1 1%	—
E272 Exfoliative (A781) Cytology	—	—	—
E285 Histopathology (A794)	—	—	—
E286 Oral Pathology (A795)	—	—	—
E294 Radiobioassay (A803)	—	—	—

* Less Than 1%

Chart No. 65

2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION I

Deficiency		Nation	Region I	ME	NH
	Facility Total	4474	346	8	15
E088	Maintenance, Inspection and Testing	1437 32%	140 40%	5 62%	10 66%
E091	Availability of Current Manuals	1134 25%	110 31%	7 87%	5 33%
E063	Procedure Manual	1072 23%	165 47%	3 37%	12 80%
E089	Monitoring Temperature Controlled Spaces	695 15%	107 30%	4 50%	3 20%
E093	Maintenance and Availability of Records	674 15%	100 28%	3 37%	5 33%
E090	Labeling of Reagents and Solutions	649 14%	106 30%	2 25%	3 20%
E068	Adequate Fire Precautions	598 13%	116 33%	3 37%	5 33%
E061	Personnel Policies	537 12%	37 10%	2 25%	3 20%
E192	(1) Control Limits Recorded/Displayed	383 8%	43 12%	2 25%	3 20%
E190	(1) Record Documents Precision	382 8%	33 9%	1 12%	33 9%
E197	(2) Screening or Qualitative Chemical	346 7%	28 8%	0	0
E078	Data for Test Performed	337 7%	67 19%	0	0
E113	(1) Each Batch of Medium Tested	315 7%	24 6%	2 25%	0
E096	Microbiology	303 6%	26 7%	1 12%	2 13%
E247	Procedure Rechecked	281 6%	45 13%	1 12%	0

Chart No. 66

2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION II

Deficiency	Nation	Region II
Facility Total	4474	467
E088 Maintenance, Inspection and Testing	1437 32%	2000 42%
E091 Availability of Current Manuals	1134 25%	119 25%
E063 Procedure Manual	1072 23%	137 29%
E089 Monitoring Temperature Controlled Spaces	695 15%	80 17%
E093 Maintenance and Availability of Records	674 15%	51 10%
E090 Labeling of Reagents and Solutions	649 14%	120 25%
E068 Adequate Fire Precautions	598 13%	69 14%
E061 Personnel Policies	537 12%	103 22%
E192 (1) Control Limits Recorded/Displayed	383 8%	101 21%
E190 (1) Record Documents Precision	382 8%	42 8%
E197 (2) Screening or Qualitative Chemical	346 7%	74 15%
E078 Data for Test Performed	337 7%	88 18%
E113 (1) Each Batch of Medium Tested	315 7%	72 15%
E096 Microbiology	303 6%	32 6%
E247 Procedure Rechecked	281 6%	60 12%

Chart No. 67 2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION III

Deficiency		Nation	Region III	DE	PA	VA
	Facility Totals	4474	481	16	275	43
E088	Maintenance, Inspection and Testing	1437 32%	129 26%	7 43%	37 13%	7 16%
E091	Availability of Current Manuals	1134 25%	119 24%	1 6%	30 10%	2 4%
E063	Precodure Manual	1072 23%	94 19%	4 25%	23 8%	4 9%
E089	Monitoring Temperature Controlled Spaces	695 15%	68 14%	2 12%	18 6%	1 2%
E093	Maintenance and Availability of Records	674 15%	88 18%	0	19 6%	3 6%
E090	Labeling of Reagents and Solutions	649 14%	62 12%	5 31%	15 5%	2 4%
E068	Adequate Fire Precautions	598 13%	61 12%	0	1	2 4%
E061	Personnel Policies	537 12%	15 3%	0	0	0
E192	(1) Control Limits Recorded/Displayed	383 8%	28 5%	3 18%	7 2%	0
E190	(1) Record Documents Precision	382 8%	27 5%	0	5 1%	382 8%
E197	(2) Screening or Qualitative Chemical	346 7%	27 5%	0	12 4%	1 2%
E078	Data for Test Performed	337 7%	19 3%	1 6%	3 1%	337 7%
E113	(1) Each Batch of Medium	315 7%	19 3%	4 25%	11 4%	19 3%
E096	Microbiology	303 6%	15 3%	2 12%	4 1%	0
E247	Procedure Rechecked	281 6%	21 4%	0	8 2%	0

Chart No. 68 2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION IV

Deficiency	Nation	Region IV	FL	GA	TN
Facility Totals	4474	646	262	81	79
E088 Maintenance, Inspection and Testing	1437 32%	153 23%	72 31%	24 29%	16 20%
E091 Availability of Current Manuals	1134 25%	168 26%	57 25%	16 19%	18 22%
E063 Precodure Manual	1072 23%	85 13%	29 12%	9 11%	2 2%
E089 Monitoring Temperature Controlled Spaces	695 15%	63 9%	28 12%	12 14%	6 7%
E093 Maintenance and Availability of Records	674 15%	161 24%	59 26%	15 18%	21 26%
E090 Labeling of Reagents and Solutions	649 14%	31 5%	21 9%	3 3%	7 8%
E068 Adequate Fire Precautions	598 13%	53 8%	23 10%	2 2%	10 12%
E061 Personnel Policies	537 12%	19 2%	1*	1 2%	0
E192 (1) Control Limits Recorded/Displayed	383 8%	26 4%	11 4%	1 1%	3 3%
E190 (1) Record Documents Precision	382 8%	40 6%	15 6%	1 1%	0
E197 (2) Screening or Qualitative Chemical	346 7%	26 4%	12 5%	6 7%	3 3%
E078 Data for Test Performed	337 7%	35 5%	13 5%	4 4%	3 3%
E113 (1) Each Batch of Medium	315 7%	35 5%	13 5%	4 4%	1 1%
E096 Microbiology	303 6%	17 2%	3 1%	2 2%	1 1%
E247 Procedure Rechecked	281 6%	13 2%	9 3%	0	1 1%

* Less than one percent

Chart No. 69 2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION V

Deficiency		Nation	Region V	MI	OH
	Facility Total	4474	581	131	141
E088	Maintenance, Inspection and Testing	1437 32%	185 31%	41 31%	41 29%
E091	Availability of Current Manuals	1134 25%	79 13%	12 9%	15 10%
E063	Procedure Manual	1072 23%	193 33%	44 33%	52 36%
E089	Monitoring Temperature Controlled Spaces	695 15%	97 16%	36 27%	20 14%
E093	Maintenance and Availability of Records	674 15%	96 16%	12 9%	23 16%
E090	Labeling of Reagents and Solutions	649 14%	85 14%	36 12%	16 11%
E068	Adequate Fire Precautions	598 13%	77 13%	33 25%	29 20%
E061	Personnel Policies	537 12%	35 6%	12 9%	1*
E192	(1) Control Limits Recorded/Displayed	383 8%	79 13%	14 10%	21 14%
E190	(1) Record Documents Precision	382 8%	30 5%	7 5%	3 2%
E197	(2) Screening or Qualitative Chemical	346 7%	26 4%	9 6%	4 2%
E078	Data for Test Performed	337 7%	30 5%	1	11 7%
E113	(1) Each Batch of Medium Tested	315 7%	26 4%	11 8%	6 4%
E096	Microbiology	303 6%	32 5%	8 6%	7 4%
E247	Procedure Rechecked	281 6%	24 4%	2 1%	11 7%

* Less than one percent

Chart No. 70

2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION VI

Deficiency	Nation	Region VI	AR	NM
Facility Total	4474	500	42	26
E088 Maintenance, Inspection and Testing	1437 32%	161 32%	2 4%	4 15%
E091 Availability of Current Manuals	1134 25%	187 37%	0	11 42%
E063 Procedure Manual	1072 23%	106 21%	1 2%	9 34%
E089 Monitoring Temperature Controlled Spaces	695 15%	103 20%	0	6 23%
E093 Maintenance and Availability of Records	674 15%	72 14%	0	12 46%
E090 Labeling of Reagents and Solutions	649 14%	73 14%	2 4%	8 30%
E068 Adequate Fire Precautions	598 13%	87 17%	9 21%	4 15%
E061 Personnel Policies	537 12%	130 26%	4 9%	5 19%
E192 (1) Control Limits Recorded/Displayed	383 8%	39 7%	0	0
E190 (1) Record Documents Precision	382 8%	59 1%	0	8 30%
E197 (2) Screening or Qualitative Chemical	346 7%	57 11%	0	5 19%
E078 Data for Test Performed	337 7%	34 6%	0	4 15%
E113 (1) Each Batch of Medium Tested	315 7%	32 6%	0	4 15%
E096 Microbiology	303 6%	20 4%	0	2 7%
E247 Procedure Rechecked	281 6%	40 8%	0	3% 11%

Chart No. 71 2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION VII, VIII & IX

Deficiency		Nation	Region VII	Region VIII	Region IX
	Facility Total	4474	181	122	995
E088	Maintenance, Inspection and Testing	1437 32%	24 13%	32 26%	384 38%
E091	Availability of Current Manuals	1134 25%	23 12%	25 20%	297 29%
E063	Procedure Manual	1072 23%	26 14%	20 16%	227 22%
E089	Monitoring Temperature Controlled Spaces	695 15%	30 16%	16 13%	112 11%
E093	Maintenance and Availability of Records	674 15%	15 8%	31 25%	39 3%
E090	Labeling of Reagents and Solutions	649 14%	5 2%	16 13%	133 13%
E068	Adequate Fire Precautions	598 13%	14 7%	17 13%	90 9%
E061	Personnel Policies	537 12%	21 11%	8 6%	169 16%
E192	(1) Control Limits Recorded/Displayed	383 8%	4 2%	4 3%	49 4%
E190	(1) Record Documents Precision	382 8%	10 5%	10 8%	128 12%
E197	(2) Screening or Qualitative Chemical	346 7%	4 2%	12 9%	88 8%
E078	Data for Test Performed	337 7%	6 3%	7 5%	48 4%
E113	(1) Each Batch of Medium Tested	315 7%	12 6	7 5%	82 8%
E096	Microbiology	303 6%	8 4%	5 4%	129 12%
E247	Procedure Rechecked	281 6%	9 4%	0	52 5%

Chart No. 72 2e

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES IN INDEPENDENT LABORATORIES

REGION X

Deficiency	Nation	Region X	AK
Facility Total	4474	155	7
E088 Maintenance, Inspection and Testing	1437 32%	29 18%	0
E091 Availability of Current Manuals	1134 25%	7 4%	1 14%
E063 Procedure Manual	1072 23%	19 12%	0
E089 Monitoring Temperature Controlled Spaces	695 15%	19 12%	0
E093 Maintenance and Availability of Records	674 15%	21 13%	3 42%
E090 Labeling of Reagents and Solutions	649 14%	12 7%	0
E068 Adequate Fire Precautions	598 13%	14 9%	1 14%
E061 Personnel Policies	537 12%	0	0
E192 (1) Control Limits Recorded/Displayed	383 8%	10 6%	0
E190 (1) Record Documents Precision	382 8%	3 1%	1 14%
E197 (2) Screening or Qualitative Chemical	346 7%	4 2%	0
E078 Data for Test Performed	337 7%	3 1%	0
E113 (1) Each Batch of Medium Tested	315 7%	6 3%	0
E096 Microbiology	303 6%	14 9%	2 28%
E247 Procedure Rechecked	281 6%	8 5%	0

Chart No. 73

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION I

Deficiency		Nation	Region I	ME	NH
	Facility Total	1443	16	6	1
E088 Maintenance, Inspection (A597) and Testing		343 24%	1 6%	0	0
E093 Maintenance and Availability (A602) of Records		304 21%	1 6%	1 17%	0
E091 Availability of Current (A600) Manual		286 20%	2 13%	1 17%	0
E089 Monitoring Temperature (A598) Controlled Spaces		217 15%	0	0	0
E063 Procedure Manual (A573)		212 15%	1 6%	0	0
E191 Standard Reference Sample (A700)		141 10%	0	0	0
E090 Labeling of Reagents and (A599) Solutions		134 9%	0	0	0
E190 Record Documents (A699) Precision		119 8%	0	0	0
E113 Each Batch of Medium (A622) Tested		109 8%	0	0	0
E077 Specimen Records (A587) Chemical		105 7%	1 6%	1 17%	0
E192 Control Limits (A701) Recorded/Displayed		104 7%	0	0	0
E247 Procedures Rechecked (A756)		94 7%	0	0	0
E032 Proficiency Testing (A551)		90 6%	1 6%	1 17%	0
E197 Screening or Qualitative (A706) Chemical		85 6%	0	0	0
E096 Microbiology (A605)		77 5%	0	0	0

Chart No. 74

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION II

Deficiency		Nation	Region II
	Facility Total	1443	45
E088 (A597)	Maintenance, Inspection and Testing	343 24%	0
E093 (A602)	Maintenance and Availability of Records	304 21%	0
E091 (A600)	Availability of Current Manuals	286 20%	0
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	0
E063 (A573)	Procedure Manual	212 15%	0
E191 (A700)	Standard Reference Sample	141 10%	0
E090 (A599)	Labeling of Reagents and Solutions	134 9%	0
E190 (A699)	Record Documents Precision	119 8%	0
E113 (A622)	Each Batch of Medium Tested	109 8%	0
E077 (A587)	Specimen Records	105 7%	0
E192 (A701)	Control Limits Recorded/Displayed	104 7%	0
E247 (A756)	Procedures Rechecked	94 7%	0
E032 (A551)	Proficiency Testing	90 6%	0
E197 (A706)	Screening or Qualitative Chemical	85 6%	0
E096 (A605)	Microbiology	77 5%	0

Chart No. 75

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION III

Deficiency	Nation	Region III	DE	PA	VA
Facility Totals	1443	43	0	14	6
E088 (A597) Maintenance, Inspection and Testing	343 24%	5 12%	0	1 7%	1 17%
E093 (A602) Maintenance and Availability of Records	304 21%	14 33%	0	0	1 17%
E091 (A600) Availability of Current Manuals	286 20%	12 28%	0	0	1 17%
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	8 19%	0	0	0
E063 (A573) Procedure Manual	212 15%	0	0	0	0
E191 (A700) Standard Reference Sample	141 10%	3 7%	0	0	0
E090 (A599) Labeling of Reagents and Solutions	134 9%	9 21%	0	0	0
E190 (A699) Record Documents Precision	119 8%	2 5%	0	0	0
E113 (A622) Each Batch of Medium Tested	109 8%	1 2%	0	0	0
E077 (A587) Specimen Records	105 7%	4 9%	0	0	0
E192 (A701) Control Limits Recorded/Displayed	104 7%	4 9%	0	0	0
E247 (A756) Procedures Rechecked	94 7%	2 5%	0	0	0
E032 (A551) Proficiency Testing	90 6%	9 21%	0	0	0
E197 (A706) Screening or Qualitative Chemical	85 6%	6 14%	0	0	0
E096 (A605) Microbiology	77 5%	0	0	0	0

Chart No. 76

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION IV

Deficiency	Nation	Region IV	FL	GA	TN
Facility Totals	1443	263	40	59	23
E088 Maintenance, Inspection (A597) and Testing	343 24%	80 30%	4 10%	26 44%	8 35%
E093 Maintenance and (A602) Availability of Records	304 21%	100 38%	11 28%	24 41%	10 43%
E091 Availability of (A600) Current Manuals	286 20%	87 33%	12 30%	26 44%	5 22%
E089 Monitoring Temperature (A598) Controlled Spaces	217 15%	31 12%	3 8%	8 14%	4 17%
E063 Procedure Manual (A573)	212 15%	42 16%	1 3%	3 5%	0
E191 Standard Reference (A700) Sample	141 10%	25 10%	1 3%	6 10%	2 7%
E090 Labeling of Reagents (A599) and Solutions	134 9%	15 6%	2 5%	0	5
E190 Record Documents (A699) Precision	119 8%	26 10%	5 13%	8 14%	0
E113 Each Batch of (A622) Medium Tested	109 8%	33 13%	3 8%	3 5%	1 4%
E077 Specimen Records (A587)	105 7%	27 10%	4 10%	4 7%	1 4%
E192 Control Limits (A701) Recorded/Displayed	104 7%	18 7%	5 13%	2 3%	1 4%
E247 Procedures Rechecked (A756)	94 7%	26 10%	1 3%	9 15%	2 7%
E032 Proficiency Testing (A551)	90 6%	13 5%	2 5%	4 7%	1 4%
E197 Screening or (A706) Qualitative Chemical	85 6%	23 9%	4 10%	10 17%	0
E096 Microbiology (A605)	77 5%	10 4%	0	5 8%	0

Chart No. 77

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION V

Deficiency		Nation	Region V	MI	OH
	Facility Total	1443	163	9	18
E088 (A597)	Maintenance, Inspection and Testing	343 24%	11 7%	0	0
E093 (A602)	Maintenance and Availability of Records	304 21%	13 8%	0	1 6%
E091 (A600)	Availability of Current Manual	286 20%	11 7%	0	3 17%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	4 2%	0	0
E063 (A573)	Procedure Manual	212 15%	8 5%	0	0
E191 (A700)	Standard Reference Sample	141 10%	LessThan 1%	0	0
E090 (A599)	Labeling of Reagents and Solutions	134 9%	7 4%	0	0
E190 (A699)	Record Documents Precision	119 8%	2 1%	0	0
E113 (A622)	Each Batch of Medium Tested	109 8%	5 3%	0	3 17%
E077 (A587)	Specimen Records Chemical	105 7%	7 4%	0	0
E192 (A701)	Control Limits Recorded/Displayed	104 7%	12 7%	0	0
E247 (A756)	Procedures Rechecked	94 7%	2 1%	0	1 6%
E032 (A551)	Proficiency Testing	90 6%	2 1%	0	0
E197 (A706)	Screening or Qualitative Chemical	85 6%	LessThan 1%	0	0
E096 (A605)	Microbiology	77 5%	5 3%	0	0

Chart No. 78

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION VI

Deficiency	Nation	Region VI	AR	NM
Facility Total	1443	306	37	18
E088 (A597) Maintenance, Inspection and Testing	343 24%	66 22%	2 5%	2 11%
E093 (A602) Maintenance and Availability of Records	304 21%	38 12%	1 3%	3 17%
E091 (A600) Availability of Current Manual	286 20%	62 20%	3 8%	6 33%
E089 (A598) Monitoring Temperature Controlled Spaces	217 15%	36 12%	1 3%	2 11%
E063 (A573) Procedure Manual	212 15%	41 13%	4 11%	2 11%
E191 (A700) Standard Reference Sample	141 10%	29 9%	2 5%	2 11%
E090 (A599) Labeling of Reagents and Solutions	134 9%	33 11%	2 5%	5 28%
E190 (A699) Record Documents Precision	119 8%	20 7%	0	3 17%
E113 (A622) Each Batch of Medium Tested	109 8%	16 5%	0	0
E077 (A587) Specimen Records Chemical	105 7%	17 6%	0	0
E192 (A701) Control Limits Recorded/Displayed	104 7%	22 7%	0	0
E247 (A756) Procedures Rechecked	94 7%	13 4%	0	1 6%
E032 (A551) Proficiency Testing	90 6%	26 8%	1 3%	1 6%
E197 (A706) Screening or Qualitative Chemical	85 6%	17 6%	1 3%	0
E096 (A605) Microbiology	77 5%	15 5%	0	2 11%

Chart No. 79

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES NON-ACCREDITED HOSPITALS

REGION VII

Deficiency		Nation	Region VII
	Facility Total	1443	232
E088 (A597)	Maintenance, Inspection and Testing	343 24%	98 42%
E093 (A602)	Maintenance and Availability of Records	304 21%	51 22%
E091 (A600)	Availability of Current Manuals	286 20%	61 26%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	80 34%
E063 (A573)	Procedure Manual	212 15%	68 29%
E191 (A700)	Standard Reference Sample	141 10%	56 24%
E090 (A599)	Labeling of Reagents and Solutions	134 9%	32 14%
E190 (A699)	Record Documents Precision	119 8%	47 20%
E113 (A622)	Each Batch of Medium Tested	109 8%	25 11%
E077 (A587)	Specimen Records	105 7%	22 9%
E192 (A701)	Control Limits Recorded/Displayed	104 7%	25 11%
E247 (A756)	Procedures Rechecked	94 7%	23 10%
E032 (A551)	Proficiency Testing	90 6%	16 7%
E197 (A706)	Screening or Qualitative Chemical	85 6%	19 8%
E096 (A605)	Microbiology	77 5%	23 10%

Chart No. 80

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES NON-ACCREDITED HOSPITALS

REGION VIII

Deficiency		Nation	Region VIII
	Facility Total	1443	183
E088 (A597)	Maintenance, Inspection and Testing	343 24%	64 35%
E093 (A602)	Maintenance and Availability of Records	304 21%	52 28%
E091 (A600)	Availability of Current Manuals	286 20%	32 17%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	32 17%
E063 (A573)	Procedure Manual	212 15%	30 16%
E191 (A700)	Standard Reference Sample	141 10%	7 4%
E090 (A599)	Labeling of Reagents and Solutions	134 9%	17 9%
E190 (A699)	Record Documents Precision	119 8%	11 6%
E113 (A622)	Each Batch of Medium Tested	109 8%	17 9%
E077 (A587)	Specimen Records	105 7%	21 11%
E192 (A701)	Control Limits Recorded/Displayed	104 7%	10 5%
E247 (A756)	Procedures Rechecked	94 7%	17 9%
E032 (A551)	Proficiency Testing	90 6%	10 5%
E197 (A706)	Screening or Qualitative Chemical	85 6%	11 6%
E096 (A605)	Microbiology	77 5%	13 7%

Chart No. 81

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES
NON-ACCREDITED HOSPITALS

REGION IX

Deficiency		Nation	Region IX
	Facility Total	1443	92
E088 (A597)	Maintenance, Inspection and Testing	343 24%	0
E093 (A602)	Maintenance and Availability of Records	304 21%	1 1%
E091 (A600)	Availability of Current Manuals	286 20%	3 3%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	6 7%
E063 (A573)	Procedure Manual	212 15%	0
E191 (A700)	Standard Reference Sample	141 10%	3 3%
E090 (A599)	Labeling of Reagents and Solutions	134 9%	4 4%
E190 (A699)	Record Documents Precision	119 8%	2 2%
E113 (A622)	Each Batch of Medium Tested	109 8%	2 2%
E077 (A587)	Specimen Records	105 7%	3 3%
E192 (A701)	Control Limits Recorded/Displayed	104 7%	0
E247 (A756)	Procedures Rechecked	94 7%	3 3%
E032 (A551)	Proficiency Testing	90 6%	4 4%
E197 (A706)	Screening or Qualitative Chemical	85 6%	3 3%
E096 (A605)	Microbiology	77 5%	3 3%

Chart No. 82

FIFTEEN MOST FREQUENTLY CITED LAB DEFICIENCIES NON-ACCREDITED HOSPITALS

REGION X

Deficiency		Nation	Region X	AK
	Facility Total	1443	100	10
E088 (A597)	Maintenance, Inspection and Testing	343 24%	18 18%	1 10%
E093 (A602)	Maintenance and Availability of Records	304 21%	34 34%	8 80%
E091 (A600)	Availability of Current Manual	286 20%	16 16%	6 60%
E089 (A598)	Monitoring Temperature Controlled Spaces	217 15%	20 20%	0
E063 (A573)	Procedure Manual	212 15%	22 22%	1 10%
E191 (A700)	Standard Reference Sample	141 10%	17 17%	2 20%
E090 (A599)	Labeling of Reagents and Solutions	134 9%	17 17%	1 10%
E190 (A699)	Record Documents Precision	119 8%	9 9%	4 4%
E113 (A622)	Each Batch of Medium Tested	109 8%	10 10%	1 10%
E077 (A587)	Specimen Records Chemical	105 7%	3 3%	0
E192 (A701)	Control Limits Recorded/Displayed	104 7%	13 13%	4 40%
E247 (A756)	Procedures Rechecked	94 7%	8 8%	0
E032 (A551)	Proficiency Testing	90 6%	9 9%	4 40%
E197 (A706)	Screening or Qualitative Chemical	85 6%	5 5%	0
E096 (A605)	Microbiology	77 5%	8 8%	2 20%

3(a) Q By region, how many facilities were surveyed as part of HCFA's federal monitoring survey of state inspection of clinical labs in the most recent year?

(a) A The number of Federal monitoring surveys (FMS) of clinical laboratories conducted in each region in FY 1987 was:

Region	Comparative Survey	Observation Survey	Total
I	15	4	19
II	1	1	2
III	7	0	7
IV	5	5	10
V	19	1	20
VI	5	2	7
VII	10	0	10
VIII	5	1	6
IX	16	1	17
X	6	1	7
			105

(b) Q By region, what were the results of this monitoring survey for the most recent year? (Please indicate the areas of disagreement, the cause of the disagreement, and the resolution.) Are these results representative of state performance in prior years?

(b) A The following information is based on deficiency data (Federal vs State survey) contained in MMACS. If the results of a FMS laboratory survey were not entered into MMACS, a comparative report (Federal vs State findings, Report 8) for that survey could not be generated.

Nationally, for FMS laboratory surveys conducted during fiscal year 1987, there was 98% agreement with State deficiency findings at the condition level, 97% agreement at the standard level and 98% agreement at the element level.

In Region I, based on 9 FMS laboratory surveys, there was 98% agreement with State deficiency findings at the condition level, 91% agreement at the standard level and 93% agreement at the element level. Areas of disagreement included proficiency testing, procedure manual, laboratory facilities, documentation and record keeping, safety precautions, maintenance of equipment and quality control. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region II, based on 1 FMS laboratory survey, there was 100% agreement with State deficiency findings at the condition level, 100% agreement at the standard level, and 100% agreement at the element level. This fiscal year's FMS results for laboratory surveys are probably not representative of State performance in prior years, because so few FMS surveys were conducted in FY'87 to accurately evaluate State survey performance.

In Region III, based on 6 FMS laboratory surveys, there was 100% agreement with State deficiency findings at the condition level, 99% agreement at the standard level, and 100% agreement at the element level. Areas of disagreement included laboratory administration by the director and laboratory procedures. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The states were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of state performance in prior years.

In Region IV, based on 3 FMS laboratory surveys, there was 88% agreement with State deficiency findings at the condition level, 94% agreement at the standard level, and 94% agreement at the element level. Areas of disagreement were laboratory director, supervision, procedure manuals, laboratory facilities, documentation and record keeping, maintenance of equipment and quality control. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys may not be representative of performance in prior years because of the small sample size of FMS laboratory surveys.

In Region V, based on 11 FMS laboratory surveys, there was 100% agreement with State deficiency findings at the condition level, 100% agreement at the standard level and 100% agreement at the element level. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region VI, based on 4 FMS laboratory surveys, there was 91% agreement with State deficiency findings at the condition level, 94% agreement at the standard level, and 97% agreement at the element level. Areas of disagreement were proficiency testing, laboratory management, documentation and record keeping, maintenance of equipment and quality control. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan or correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region VII, based on 8 FMS laboratory surveys, there was 100% agreement with State deficiency findings at the condition level, 98% agreement at the standard level and 98% agreement at the element level. Areas of disagreement were proficiency testing, personnel policies, documentation and record keeping, and quality control. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region VIII, based on 4 FMS laboratory surveys, there was 100% agreement with State deficiency findings at the condition level, 93% agreement at the standard level and 98% agreement at the element level. Areas of disagreement were general supervision, personnel policies, laboratory facilities, documentation and record keeping and maintenance of equipment. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region IX, based on 11 FMS laboratory surveys, there was 96% agreement with State deficiency findings at the condition level, 96% agreement at the standard level, and 100% agreement at the element level. Areas of disagreement were laboratory director, supervision, (general and technical), procedure manual, laboratory facilities and quality control. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan of correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

In Region X, based on 4 FMS laboratory surveys, there was 100% agreement with State deficiency findings at the condition level, 99% agreement at the standard level and 100% agreement at the element level. Areas of disagreement were quality control and safety precautions. The cause of disagreement is not available from our data system. Disagreements between the Federal and State findings were resolved by instructing the State to take corrective action for the problems found concerning the State's interpretation or survey activity relating to the areas of disagreement. The States were also instructed to follow up on the Federal survey findings by either obtaining a plan or correction from the laboratory for the deficiencies cited by the Federal surveyor or by verifying correction of the deficiencies during the State's next scheduled visit. This fiscal year's FMS results for laboratory surveys are representative of State performance in prior years.

4. Q What is the range of actions HCFA can take against a federally regulated lab that is not exempted from CLIA through CAP accreditation or deemed under Medicare through the Joint Commission based on the lab's survey results? How often has each available sanction been used?

A Laboratories that are Federally regulated (those not exempted from CLIA through CAP accreditation or hospital laboratories deemed to meet Medicare's requirements through the Joint Commission) include Medicare approved independent laboratories, CLIA licensed laboratories (independent and hospital labs) and nonaccredited hospital laboratories. Actions that HCFA can take against an independent laboratory approved for Medicare when it fails to meet all the conditions for coverage of services are to terminate the laboratory's approval for all services it performs or to terminate the laboratory's approval for services it performs in a laboratory specialty or subspecialty.

Actions HCFA can take against a laboratory that is licensed under CLIA are to revoke the laboratory's CLIA license in total or to limit the laboratory's CLIA license by excluding all tests performed in a specialty or subspecialty, or to limit the laboratory's CLIA license by excluding individual tests.

In a nonaccredited hospital, if the condition for laboratory services is found to be out of compliance, HCFA can terminate the entire hospital. No action is taken against the laboratory itself because the hospital as a whole is approved for Medicare, and the individual departments (of which laboratory services is one) are not individually approved.

Charts 83 through 85 show the independent laboratories terminated from the Medicare program and laboratories with revoked or limited CLIA licenses.

Chart No. 83

Independent Laboratories Terminated For All Services from the Medicare Program

Termination Action	Merger/ Closure FY '85	'86	'87	Dissatisfaction with Reimbursement FY '85	'86	'87	Risk of Involuntary Termination FY '85	'86	'87	Other Reasons for Withdrawal FY '85	'86	'87	Failure to meet health/ Safety FY '85	'86	'87	Totals FY '85	'86	'87
FY '85 Nationally	210	206	192	15	2	3	13	6	6	90	44	31	10	11	14	338	269	246
Region I	13	20	19	0	1	0	1	0	0	10	3	3	0	1	0	24	25	22
ME	3	5	0	0	1	0	0	0	0	0	0	0	0	0	0	3	6	0
NH	0	2	1	0	0	0	0	0	0	1	0	0	0	0	0	1	2	1
Region II	20	17	12	2	0	0	1	2	0	3	0	0	1	2	4	27	21	16
Region III	23	17	24	0	0	0	1	0	0	7	6	7	2	1	0	33	24	31
DE	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0
PA	13	13	16	0	0	0	1	0	0	6	2	7	0	0	0	20	15	23
VA	2	1	1	0	0	0	0	0	0	1	1	0	0	1	0	3	3	0
Region IV	18	31	27	0	0	0	0	0	1	15	7	5	1	0	1	30	38	34
FL	9	14	10		0	0	0	0	1	5	2	1	1	0	1	14	16	13
GA	2	4	7	0	0	0	0	0	0	5	4	1	0	0	0	7	8	8
TN	1	4	3	0	0	0	0	0	0	0	0	0	0	0	0	1	4	3
Region V	36	28	38	1	0	1	2	1	3	7	4	5	4	5	9	50	38	56
MI	4	10	19	0	0	0	2	1	0	3	0	0	1	0	1	10	11	20
OH	10	5	3	0	0	0	0	0	0	1	2	1	1	1	1	12	8	5
Region VI	26	16	19	4	0	1	1	1	1	10	4	5	2	1	0	43	22	26
AR	2	1	3	1	0	0	0	0	1	0	1	0	0	0	0	3	2	4
NM	1	0	0	1	0	0	0	0	0	1	0	4	1	0	0	4	0	4
Region VII	11	6	5	0	0	0	0	0	0	4	0	2	0	0	0	15	6	7
Region VIII	2	2	2	0	0	1	0	0	1	13	5	2	0	0	0	15	7	6
Region IX	53	67	43	8	1	0	7	2	0	15	7	1	0	0	0	63	77	44
Region X	8	2	3	0	0	0	0	0	0	6	8	1	0	0	0	14	10	4
AK	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1

Chart No. 84

Independent Laboratories with (SUB)Specialities deleted based on Current Survey

Laboratory Specialty:	Histocompatibility	Microbiology	Serology	Chemistry	Hematology	Immunohematology	Pathology
Nationally	3	136	110	102	14	77	49
Region I	0	18	15	21	3	13	5
ME	0	1	0	0	0	1	0
NH	0	0	1	1	0	1	0
Region II	0	3	2	1	0	2	4
Region III	0	11	8	13	1	4	4
DE	0	1	1	0	0	0	0
PA	0	6	7	12	1	3	2
VA	0	0	0	0	0	0	0
Region IV	1	17	22	10	3	5	4
FL	0	8	12	6	2	3	2
GA	0	3	2	2	2	0	1
TN	1	3	2	0	0	0	0
Region V	0	24	9	11	1	8	7
MI	4	4	0	0	0	1	1
OH	0	3	0	3	0	2	3
Region VI	2	17	18	19	2	10	5
AR	0	1	3	1	1	3	0
NM	0	1	1	0	0	0	1
Region VII	0	3	5	1	2	3	2
Region VIII	0	4	2	3	1	0	2
Region IX	0	29	23	19	1	28	12
Region X	0	10	6	4	0	4	3
AK	0	0	0	0	0	0	0

NOTE: Deletions may be of the entire specialty or only subspecialty(s) under the specialty.
Deletions may be due to voluntary or involuntary terminations.

Chart No. 85

LABORATORIES WITH REVOKED OR LIMITED CLIA LICENSES

YEAR	ALL SERVICES	BACTERIOLOGY	MYCOLOGY	PARASITOLOGY	HEMATOLOGY	1 TEST	2-4 TESTS	5 or More TESTS
83	1	1	0	4	0	18	5	2
84	1	4	2	10	0	34	20	0
85	3	1	4	2	1	37	7	0
86	3	3	2	3	0	21	8	3
87	1	0	0	0	0	0	0	0

CLIA Adverse Actions 9/79 - 6/86

Initial Notices Sent to Laboratories	CLIA Licenses Limitations	Withdrawals of Adverse Actions
852	290	239

5(a) Q How does HCFA validate the CAP and Joint Commission accreditation programs? Please provide copies of any validation or monitoring studies for these programs.

(a) A HCFA validates the Joint Commission accreditation program by conducting surveys of accredited hospitals on a selective sample basis or in response to substantial allegations of significant deficiencies. (Hospitals are certified as a whole entity, the individual hospital departments (such as laboratory services) are not certified separately.) Laboratory services is one of the thirteen areas inspected during a validation survey. Since we have not granted CAP deemed status for Medicare certification of laboratories, we hold the Joint Commission responsible for those laboratories accredited by CAP and located in Joint Commission accredited hospitals. If as a result of sample or allegation onsite surveys, Joint Commission hospital laboratories are found out of compliance with Medicare requirements, the hospital must correct the deficiencies in order to continue to participate in Medicare. Non-compliant accredited hospitals are placed under State agency monitoring during the process of correcting the deficiencies.

Each year a comparative analysis of the validation survey findings and the Joint Commission survey findings is prepared for the annual report to Congress. Even though the State survey agency may find deficiencies in the laboratories accredited by CAP, we do not compare these findings to those of CAP for the annual report to Congress because CAP is not deemed for Medicare. However, if problems are found which are significant enough to make non-compliance determinations in the CAP accredited laboratories, we informally notify the Joint Commission and ask them to follow up on the validation findings just as we do for all problems found in the sample validation of Joint Commission hospitals. Attached is Fiscal Year 1984 "Report on Medicare Validation Surveys of Hospitals Accredited by the Joint Commission on Accreditation of Hospitals (JCAH)."

(b) Q What is the range of actions HCFA can take against a CAP-accredited lab or a Joint Commission Medicare-deemed hospital lab based on the lab's survey results? How often has each available sanction been used? Is the only recourse for HCFA against a Joint Commission hospital lab to decertify the entire hospital?

(b) A HCFA does not take any actions against a Joint Commission hospital's laboratory per se. The action is taken against the entire hospital. If the condition of laboratory services is found out of compliance as a result of the validation survey, the hospital can agree to send the laboratory testing to another approved laboratory until the hospital has corrected the problems. (This will keep the hospital from being terminated, or being placed under State agency monitoring if laboratory services is the only condition found out of compliance during the survey).

If deficiencies found during the validation survey are considered a serious and immediate threat to health and safety of patients, termination procedures against the hospital are initiated. Otherwise, if a condition(s) is found out of compliance, the hospital is placed under State agency monitoring. The hospital continues to be accredited by its accrediting agency, and the State agency assumes full survey responsibility while the hospital corrects the deficiencies. The hospital remains under State agency monitoring until all conditions of participation are in compliance or until termination. The following chart lists the number of Joint Commission accredited hospitals that were placed under State agency monitoring because the condition of laboratory services was found to be out of compliance (other conditions may have also been found out of compliance). Figures are not available for 1987.

	Number of Hospitals Placed Under State Agency Monitoring	Sample Size Surveyed	Percentage of Sample Placed Under State Agency Monitoring
1984	4	46	9%
1985	3	66	5%
1986	4	66	8%

(c) Q How many CAP-accredited labs or Joint Commission Medicare-deemed hospital labs have lost CAP or Joint Commission accreditation in the past five years? What action did HCFA take against these labs?

(c) A We do not have information concerning the number of CAP accredited laboratories in Joint Commission accredited hospitals that lost their CAP accreditation. Loss of CAP accreditation by a Joint Commission accredited hospital laboratory would be an issue for the Joint Commission, since it would be responsible for inspecting any laboratory located in a Joint Commission accredited hospital that lost its CAP accreditation. HCFA would not take any action against a laboratory that lost its CAP accreditation because CAP does not have deemed status for Medicare and in a hospital an action is not taken against the laboratory per se, but against the entire hospital.

If a hospital lost its Joint Commission accreditation, the hospital would be placed under State agency monitoring. No action would be taken against the hospital unless conditions were found out of compliance during the State agency survey and termination procedures were initiated. We do not have information in our automated data system reflecting the number of Joint Commission accredited hospitals that lost their accreditation because of problems identified in the laboratory area.

6(a) Q We understand that the survey data reported by the states in MMACS includes information on proficiency testing performance for clinical laboratories (codes E34-E54). Among all the labs for which proficiency testing data was reported for the most recent survey, by region and nationally, (1) how many and (2) what per cent:

-- received a satisfactory ranking for all proficiency testing performed for all specialties and subspecialties?

-- received an unsatisfactory ranking for at least one specialty or subspecialty?

-- received an unsatisfactory ranking for three or more specialties or subspecialties?

(b) Q Please list for each specialty and subspecialty the number and per cent of labs which received a satisfactory ranking for that specific specialty and subspecialty (frequencies for E34-E54 individually, with 100 per cent for each specialty or subspecialty being those labs with proficiency test results for that specialty or subspecialty).

6(a)(b) A Charts 86 through 102 list information on proficiency testing performance for independent laboratories and non-accredited hospital laboratories. Data for Medicare only independent laboratories and Medicare independent/CLIA laboratories is included in the charts labeled independent laboratories. Proficiency testing performance for CLIA only laboratories is not included (MMACS is not programmed to capture data for CLIA only laboratories).

The charts labeled non-accredited hospital laboratories only include proficiency testing performance data on non-accredited hospital laboratories. We do not have data on proficiency testing performance in accredited hospital laboratories.

Charts 86 through 87 list overall proficiency testing data for independent laboratories and non-accredited hospital laboratories. Charts 88 through 102 list the number of independent and non-accredited hospital laboratories with satisfactory proficiency testing performance for specific laboratory specialty(ies) and subspecialty(ies).

The data in these charts is based on the most current survey. We do not have data on proficiency testing performance for cytology, histopathology and oral pathology because we have not approved a proficiency testing program for these subspecialties for Medicare/CLIA regulatory purposes.

Chart No. 86

6(a)

PROFICIENCY TESTING PERFORMANCE OF INDEPENDENT LABORATORIES FOR ALL (SUB)SPECIALTIES BASED ON THE MOST CURRENT SURVEY

	Total number of Laboratories	Satisfactory Performance in all (Sub)specialties		Unsatisfactory Performance in at least one (Sub)specialty		Unsatisfactory Performance in three or more (sub)specialties	
National	4363	3968	91%	143	3%	31	1%
Region I	337	312	93%	8	2%	1	less than 1%
ME	7	7	100%	0		0	
NH	15	11	73%	0		0	
Region II	449	404	90%	30	7%	6	1%
Region III	471	439	93%	2	Less than 1%	0	
DE	17	17	100%	0		0	
PA	263	258	98%	1	Less than 1%	0	
VA	44	39	89%	0		0	
Region IV	642	588	92%	2	Less than 1%	1	Less than 1%
FL	224	212	95%	2	1%	1	Less than 1%
GA	82	80	98%	0		0	
TN	77	73	95%	0		0	
Region V	562	480	86%	23	4%	8	1%
ME	128	84	66%	16	13%	8	6%
OH	137	118	86%	5	4%	0	
Region VI	496	434	88%	15	3%	3	1%
AR	36	36	100%	0		0	
NM	26	21	81%	2	8%	0	
Region VII	174	156	90%	6	3%	2	1%
Region VIII	121	114	94%	1	1%	0	
Region IX	960	906	94%	18	2%	1	Less than 1%
Region X	151	135	89%	2	1%	0	
AK	7	6	86%	0		0	

Chart No. 87

PROFICIENCY TESTING PERFORMANCE OF NON-ACCREDITED HOSPITAL LABORATORIES FOR ALL (SUB)SPECIALTIES BASED ON THE MOST CURRENT SURVEY

	Total Number of Hospital Labs	Satisfactory Performance in all (Sub)specialties		Unsatisfactory Performance in at least one (Sub)specialty		Unsatisfactory Performance in three or more (sub)specialties	
National	1416	1332	94%	34	2%	8	
Region I	15	14	93%	1	70%	0	
ME	6	5	83%	1	17%	0	
NH	1	1	100%	0		0	
Region II	43	41	95%	2	5%	0	
Region III	44	44	100%	0		0	
DE	0	0		0		0	
PA	15	15	100%	0		0	
VA	6	6	100%	0		0	
Region IV	261	252	97%	2	1%	0	
FL	38	38	100%	0		0	
GA	59	51	86%	2	3%	0	
TN	23	23	100%	0		0	
Region V	160	150	94%	1	1%	0	
ME	9	9	100%	0		0	
OH	18	18	100%	1	6%	0	
Region VI	301	279	93%	16	5%	5	2%
AR	37	36	97%	0		0	
NM	17	16	94%	1	6%	0	
Region VII	228	203	89%	8	4%	1	Less than 1%
Region VIII	178	166	93%	2	1%	1	Less than 1%
Region IX	88	87	99%	0		0	
Region X	98	96	98%	2	2%	2	2%
AK	10	10	100%	0		0	

Chart No. 88 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region I

Deficiency	Nation	Region I	Region ME	Region NH
Facility Total	4474	346	8	15
E34 Bacteriology	1708 38%	115 33%	4 50%	6 40%
E35 Mycobacteriology	198 4%	6 2%	1 13%	3 20%
E36 Mycology	263 6%	10 3%	4 50%	1 7%
E37 Parasitology	1052 24%	37 11%	4 50%	3 20%
E38 Virology	156 3%	9 3%	0	1 7%
E39 Immunology	456 10%	37 11%	5 63%	2 13%
E40 Syphilis Serology	1859 42%	109 31%	4 50%	5 33%
E41 Non Syphilis Serology	2651 59%	212 61%	6 75%	8 53%
E42 Chemistry	2738 61%	231 67%	8 100%	11 73%
E43 Endocrinology	1040 23%	120 35%	5 63%	1 7%
E44 Toxicology	1000 22%	103 30%	6 75%	2 13%
E45 Urinalysis	2495 56%	216 62%	5 63%	10 67%
E46 Immunohematology	590 13%	31 9%	0	2 13%
E47 ABO Grouping/RH Typing	1156 26%	53 15%	2 25%	2 13%
E48 Atypical Antibody	840 19%	44 13%	2 25%	2 13%
E49 Compatibility Testing	222 5%	5 1%	0	0
E50 Hematology	2750 62%	238 69%	4 50%	9 60%
E51 Radiobioassay	123 3%	3 1%	0	0
E52 Exfoliative Cytology	107 2%	1 1%	0	0
E53 Histopathology	44 1%	0	0	0
E54 Oral Pathology	28 1%	0	0	0

Chart No. 89 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region II

Deficiency		Nation	Region II
	Facility Total	4474	467
E34	Bacteriology	1708 38%	220 47%
E35	Mycobacteriology	198 4%	11 2%
E36	Mycology	263 6%	13 3%
E37	Parasitology	1052 24%	149 32%
E38	Virology	156 3%	5 1%
E39	Immunology	456 10%	9 2%
E40	Syphilis Serology	1859 42%	250 54%
E41	Non Syphilis Serology	2651 59%	285 61%
E42	Chemistry	2738 61%	346 74%
E43	Endocrinology	1040 23%	99 21%
E44	Toxicology	1000 22%	85 18%
E45	Urinalysis	2495 56%	296 63%
E46	Immunohematology	590 13%	50 11%
E47	ABO Grouping/RH Typing	1156 26%	155 33%
E48	Atypical Antibody	840 19%	84 18%
E49	Compatibility Testing	222 5%	11 2%
E50	Hematology	2750 62%	358 77%
E51	Radiobioassay	123 3%	1 1%
E52	Exfoliative Cytology	107 2%	56 12%
E53	Histopathology	44 1%	4 1%
E54	Oral Pathology	28 1%	1 1%

Chart No. 90 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region III

Deficiency		Nation	Region III	DE	PA	VA
	Facility Total	4474	481	16	275	43
E34	Bacteriology	1708 38%	170 35%	8 50%	87 32%	18 42%
E35	Mycobacteriology	198 4%	23 5%	1 6%	17 6%	1 6%
E36	Mycology	263 6%	27 6%	1 6%	15 5%	2 5%
E37	Parasitology	1052 24%	68 14%	4 25%	25 9%	9 21%
E38	Virology	156 3%	15 3%	0	8 3%	1 6%
E39	Immunology	456 10%	13 3%	0	7 3%	0
E40	Syphilis Serology	1859 42%	178 37%	6 38%	99 36%	28 65%
E41	Non Syphilis Serology	2651 59%	267 56%	13 81%	149 54%	29 67%
E42	Chemistry	2738 61%	222 46%	15 94%	185 67%	20 47%
E43	Endocrinology	1040 23%	95 20%	0	41 15%	14 33%
E44	Toxicology	1000 22%	105 22%	5 31%	60 22%	14 33%
E45	Urinalysis	2495 56%	261 54%	14 88%	146 53%	19 44%
E46	Immunohematology	590 13%	48 10%	4 25%	28 10%	3 7%
E47	ABO Grouping/RH Typing	1156 26%	59 12%	3 19%	28 10%	12 28%
E48	Atypical Antibody	840 19%	27 6%	0	18 7%	3 7%
E49	Compatibility Testing	222 5%	15 3%	0	7 3%	3 7%
E50	Hematology	2750 62%	289 60%	15 94%	169 61%	21 49%
E51	Radiobioassay	123 3%	14 3%	1 6%	6 2%	0
E52	Exfoliative Cytology	107 2%	14 3%	0	6 2%	6 14%
E53	Histopathology	44 1%	10 2%	0	4 1%	6 14%
E54	Oral Pathology	28 1%	6 1%	0	3 1%	3 7%

Chart No. 91 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region IV

Deficiency		Nation	Region IV	FL	GA	TN
	Facility Total	4474	646	262	81	79
E34	Bacteriology	1708 38%	183 28%	71 27%	20 25%	19 24%
E35	Mycobacteriology	198 4%	32 5%	13 5%	4 5%	3 4%
E36	Mycology	263 6%	37 6%	14 5%	1 1%	5 6%
E37	Parasitology	1052 24%	111 17%	48 18%	12 15%	9 11%
E38	Virology	156 3%	18 3%	9 3%	1 1%	4 5%
E39	Immunology	456 10%	50 89%	20 8%	9 11%	3 4%
E40	Syphilis Serology	1859 42%	230 36%	90 34%	34 42%	18 23%
E41	Non Syphilis Serology	2651 59%	322 50%	119 45%	38 47%	31 39%
E42	Chemistry	2738 61%	315 49%	120 46%	34 42%	30 38%
E43	Endocrinology	1040 23%	75 12%	13 5%	6 7%	7 9%
E44	Toxicology	1000 22%	106 16%	25 10%	12 15%	11 14%
E45	Urinalysis	2495 56%	291 45%	108 41%	22 27%	27 34%
E46	Immunohematology	590 13%	67 10%	8 3%	10 12%	5 6%
E47	ABO Grouping/RH Typing	1156 26%	124 19%	29 11%	19 23%	14 18%
E48	Atypical Antibody	840 19%	83 13%	5 2%	18 22%	10 13%
E49	Compatibility Testing	222 5%	35 5%	5 2%	3 4%	3 4%
E50	Hematology	2750 62%	303 47%	114 44%	40 50%	30 38%
E51	Radiobioassay	123 3%	27 4%	22 8%	4 5%	1 1%
E52	Exfoliative Cytology	107 2%	7 1%	2 1%	0	0
E53	Histopathology	44 1%	3 1%	0	0	0
E54	Oral Pathology	28 1%	3 1%	0	0	0

Chart No. 92 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region V

Deficiency	Nation	Region V	MI	OH
Facility Total	4474	581	131	141
E34 Bacteriology	1708 38%	290 50%	120 92%	43 30%
E35 Mycobacteriology	198 4%	31 5%	10 8%	2 1%
E36 Mycology	263 6%	55 9%	22 18%	5 4%
E37 Parasitology	1052 24%	132 23%	60 46%	22 16%
E38 Virology	156 3%	30 5%	9 7%	6 4%
E39 Immunology	456 10%	55 9%	5 4%	5 4%
E40 Syphilis Serology	1859 42%	334 57%	113 86%	46 33%
E41 Non Syphilis Serology	2651 59%	412 71%	131 100%	69 49%
E42 Chemistry	2738 61%	423 73%	131 100%	77 55%
E43 Endocrinology	1040 23%	231 40%	107 82%	29 21%
E44 Toxicology	1000 22%	236 41%	83 63%	39 28%
E45 Urinalysis	2495 56%	343 59%	81 62%	73 52%
E46 Immunohematology	590 13%	76 13%	5 4%	9 6%
E47 ABO Grouping/RH Typing	1156 26%	194 33%	63 48%	35 25%
E48 Atypical Antibody	840 19%	128 22%	57 44%	8 6%
E49 Compatibility Testing	222 5%	47 8%	16 12%	7 5%
E50 Hematology	2750 62%	420 72%	131 100%	71 50%
E51 Radiobioassay	123 3%	39 7%	2 2%	2 1%
E52 Exfoliative Cytology	107 2%	2 1%	0	0
E53 Histopathology	44 1%	5 1%	2 2%	0
E54 Oral Pathology	28 1%	0	0	0

Chart No. 93 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region VI

Deficiency		Nation	Region VI	AR	NM
	Facility Total	4474	500	42	20
E34	Bacteriology	1708 38%	164 33%	14 33%	13 65%
E35	Mycobacteriology	198 4%	29 6%	1 2%	4 20%
E36	Mycology	263 6%	39 8%	2 5%	4 20%
E37	Parasitology	1052 24%	131 26%	8 19%	10 50%
E38	Virology	156 3%	29 6%	1 2%	3 15%
E39	Immunology	456 10%	101 20%	13 31%	9 45%
E40	Syphilis Serology	1859 42%	211 42%	10 24%	20 100%
E41	Non Syphilis Serology	2651 59%	295 59%	17 40%	20 100%
E42	Chemistry	2738 61%	275 55%	23 55%	17 85%
E43	Endocrinology	1040 23%	129 26%	11 26%	12 60%
E44	Toxicology	1000 22%	128 26%	11 26%	9 45%
E45	Urinalysis	2495 56%	275 55%	20 48%	19 95%
E46	Immunohematology	590 13%	79 16%	8 19%	9 45%
E47	ABO Grouping/RH Typing	1156 26%	134 27%	8 19%	10 50%
E48	Atypical Antibody	840 19%	115 23%	6 14%	10 50%
E49	Compatibility Testing	222 5%	38 8%	3 7%	3 15%
E50	Hematology	2750 62%	280 56%	21 50%	20 100%
E51	Radiobioassay	123 3%	4 1%	1 2%	0
E52	Exfoliative Cytology	107 2%	9 2%	1 2%	0
E53	Histopathology	44 1%	7 1%	0	0
E54	Oral Pathology	28 1%	6 1%	0	0

Chart No. 94 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region VII, VIII, IX

Deficiency		Nation	Region VII	Region VIII	Region IX
	Facility Total	4474	181	122	995
E34	Bacteriology	1708 38%	53 29%	59 48%	409 41%
E35	Mycobacteriology	198 4%	8 4%	7 6%	46 5%
E36	Mycology	263 6%	11 6%	10 8%	53 5%
E37	Parasitology	1052 24%	38 21%	37 30%	314 32%
E38	Virology	156 3%	7 4%	9 7%	30 3%
E39	Immunology	456 10%	18 10%	38 31%	111 11%
E40	Syphilis Serology	1859 42%	68 38%	45 37%	401 40%
E41	Non Syphilis Serology	2651 59%	116 64%	75 62%	617 62%
E42	Chemistry	2738 61%	96 53%	76 62%	626 63%
E43	Endocrinology	1040 23%	58 32%	34 28%	180 18%
E44	Toxicology	1000 22%	57 31%	36 30%	124 13%
E45	Urinalysis	2495 56%	92 51%	62 51%	610 61%
E46	Immunohematology	590 13%	41 23%	38 31%	137 14%
E47	ABO Grouping/RH Typing	1156 26%	61 34%	44 36%	300 30%
E48	Atypical Antibody	840 19%	57 31%	40 33%	231 23%
E49	Compatibility Testing	222 5%	24 13%	12 10%	31 3%
E50	Hematology	2750 62%	100 55%	69 57%	644 65%
E51	Radiobioassay	123 3%	4 2%	7 6%	20 2%
E52	Exfoliative Cytology	107 2%	2 1%	14 12%	2 1*
E53	Histopathology	44 1%	3 2%	10 8%	2 0%
E54	Oral Pathology	28 1%	1 1%	11 9%	0

* Less than one percent

Chart No. 95 6(b)

Independent Laboratories with Satisfactory Performance in Proficiency Testing for Specific (Sub)Specialties

Region X

Deficiency		Nation	Region X	AK
	Facility Total	4474	155	7
E34	Bacteriology	1708 38%	45 29%	6 86%
E35	Mycobacteriology	198 4%	5 3%	0
E36	Mycology	263 6%	8 5%	0
E37	Parasitology	1052 24%	35 23%	1 14%
E38	Virology	156 3%	5 3%	0
E39	Immunology	456 10%	24 16%	3 43%
E40	Syphilis Serology	1859 42%	33 21%	3 43%
E41	Non Syphilis Serology	2651 59%	50 32%	5 71%
E42	Chemistry	2738 61%	46 30%	7 100%
E43	Endocrinology	1040 23%	19 12%	5 71%
E44	Toxicology	1000 22%	20 13%	2 29%
E45	Urinalysis	2495 56%	49 32%	7 100%
E46	Immunohematology	590 13%	23 15%	1 14%
E47	ABO Grouping/RH Typing	1156 26%	32 21%	3 43%
E48	Atypical Antibody	840 19%	29 19%	2 29%
E49	Compatibility Testing	222 5%	4 3%	0
E50	Hematology	2750 62%	49 32%	7 100%
E51	Radiobioassay	123 3%	4 3%	0
E52	Exfoliative Cytology	107 2%	0	0
E53	Histopathology	44 1%	0	0
E54	Oral Pathology	28 1%	0	0

Chart No. 95 a   6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region I	ME	NH
Facility Total	1416	15	6	1
E34 Bacteriology (A552)	210 15%	-	-	-
E35 Mycobacteriology (A553)	72 5%	4 25%	4 67%	-
E36 Mycology (A554)	50 4%	-	-	-
E37 Parasitology (A555)	106 7%	2 13%	2 33%	-
E38 Virology (A556)	31 2%	2 13%	2 33%	-
E39 Immunology (A557)	84 6%	2 13%	2 33%	-
E40 Syphilis Serology (A558)	144 10%	-	-	-
E41 Non Syphilis Serology (A559)	252 18%	-	-	-
E42 Chemistry (A560)	268 19%	-	-	-
E43 Endocrinology (A561)	126 9%	4 25%	4 67%	-
E44 Toxicology (A562)	129 9%	2 13%	2 33%	-
E45 Urinalysis (A563)	322 23%	3 19%	3 50%	-
E46 Immunohematology (A564)	195 14%	3 19%	3 50%	-
E47 ABO Grouping/RH Typing (A565)	253 18%	1 6%	1 17%	-
E48 Atypical Antibody (A566)	176 12%	-	-	-
E49 Compatibility Testing (A567)	229 16%	1 6%	1 17%	-
E50 Hematology (A568)	259 18%	-	-	-
E51 Radiobioassay (A569)	8 1%	-	-	-
E52 Exfoliative Cytology (A570)	6*	-	-	-
E53 Histopathology (A571)	1*	-	-	-
E51 Oral Pathology (A572)	4*	-	-	-

* - Less Than 1%.

Chart No. 96 6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory
Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region II
Facility Total	1416	43
E34 Bacteriology (A552)	210 15%	-
E35 Mycobacteriology (A553)	72 5%	11 25%
E36 Mycology (A554)	50 4%	10 23%
E37 Parasitology (A555)	106 7%	11 25%
E38 Virology (A556)	31 2%	1 2%
E39 Immunology (A557)	84 6%	1 2%
E40 Syphilis Serology (A558)	144 10%	-
E41 Non Syphilis Serology (A559)	252 18%	1 2%
E42 Chemistry (A560)	268 19%	1 2%
E43 Endocrinology (A561)	126 9%	3 7%
E44 Toxicology (A562)	129 9%	5 11%
E45 Urinalysis (A563)	322 23%	3 7%
E46 Immunohematology (A564)	195 14%	2 5%
E47 ABO Grouping/RH Typing (A565)	253 18%	-
E48 Atypical Antibody (A566)	176 12%	2 5%
E49 Compatibility Testing (A567)	229 16%	2 5%
E50 Hematology (A568)	259 18%	3 7%
E51 Radiobioassay (A569)	8 1%	2 5%
E52 Exfoliative Cytology (A570)	6*	2 5%
E53 Histopathology (A571)	1*	-
E51 Oral Pathology (A572)	4*	2 5%

* - Less Than 1%.

Chart No. 97 5(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region III	DE	PA	VA
Facility Total	1416	44	0	15	6
E34 Bacteriology (A552)	210 15%	4 9%	-	-	-
E35 Mycobacteriology (A553)	72 5%	-	-	-	-
E36 Mycology (A554)	50 4%	-	-	-	-
E37 Parasitology (A555)	106 7%	2 5%	-	-	-
E38 Virology (A556)	31 2%	5 11%	-	-	-
E39 Immunology (A557)	84 6%	2 5%	-	-	-
E40 Syphilis Serology (A558)	144 10%	5 11%	-	-	-
E41 Non Syphilis Serology (A559)	252 18%	5 11%	-	-	-
E42 Chemistry (A560)	268 19%	5 11%	-	-	-
E43 Endocrinology (A561)	126 9%	9 20%	-	-	-
E44 Toxicology (A562)	129 9%	3 7%	-	-	-
E45 Urinalysis (A563)	322 23%	10 23%	-	-	-
E46 Immunohematology (A564)	195 14%	5 11%	-	-	-
E47 ABO Grouping/RH Typing (A565)	253 18%	5 11%	-	-	-
E48 Atypical Antibody (A566)	176 12%	5 11%	-	-	-
E49 Compatibility Testing (A567)	229 16%	5 11%	-	-	-
E50 Hematology (A568)	259 18%	8 18%	-	-	-
E51 Radiobioassay (A569)	8 1%	-	-	-	-
E52 Exfoliative Cytology (A570)	6*	-	-	-	-
E53 Histopathology (A571)	1*	-	-	-	-
E51 Oral Pathology (A572)	4*	-	-	-	-

* - Less Than 1%.

Chart No. 98 5(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region IV	FL	GA	TN
Facility Total	1416	261	38	59	23
E34 Bacteriology (A552)	210 15%	30 11%	-	9 15%	2 9%
E35 Mycobacteriology (A553)	72 5%	10 4%	-	10 17%	-
E36 Mycology (A554)	50 4%	7 3%	-	7 12%	-
E37 Parasitology (A555)	106 7%	21 8%	-	8 13%	1 4%
E38 Virology (A556)	31 2%	5 2%	-	3 5%	-
E39 Immunology (A557)	84 6%	5 2%	-	4 7%	-
E40 Syphilis Serology (A558)	144 10%	50 19%	1 3%	22 37%	-
E41 Non Syphilis Serology (A559)	252 18%	50 19%	2 5%	15 25%	2 9%
E42 Chemistry (A560)	268 19%	55 21%	6 16%	14 23%	3 13%
E43 Endocrinology (A561)	126 9%	13 5%	2 5%	8 13%	-
E44 Toxicology (A562)	129 9%	11 4%	-	7 12%	-
E45 Urinalysis (A563)	322 23%	56 21%	4 11%	17 28%	3 13%
E46 Immunohematology (A564)	195 14%	23 9%	1 3%	7 12%	1 4%
E47 ABO Grouping/RH Typing (A565)	253 18%	47 18%	-	15 25%	2 9%
E48 Atypical Antibody (A566)	176 12%	23 9%	-	5 8%	1 4%
E49 Compatibility Testing (A567)	229 16%	41 16%	-	13 22%	2 9%
E50 Hematology (A568)	259 18%	51 19%	4 11%	13 22%	3 13%
E51 Radiobioassay (A569)	8 1%	2 1%	-	-	-
E52 Exfoliative Cytology (A570)	6*	1*	-	1 2%	-
E53 Histopathology (A571)	1*	-	-	-	-
E51 Oral Pathology (A572)	4*	2 1%	-	-	-

* - Less Than 1%.

Chart No. 99 6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region V	MI	OH
Facility Total	1416	160	9	18
E34 Bacteriology (A552)	210 15%	18 11%	-	1 6%
E35 Mycobacteriology (A553)	72 5%	3 2%	-	1 6%
E36 Mycology (A554)	50 4%	-	-	-
E37 Parasitology (A555)	106 7%	5 3%	-	-
E38 Virology (A556)	31 2%	4 3%	-	-
E39 Immunology (A557)	84 6%	7 4%	-	-
E40 Syphilis Serology (A558)	144 10%	8 5%	-	1 6%
E41 Non Syphilis Serology (A559)	252 18%	22 14%	-	1 6%
E42 Chemistry (A560)	268 19%	23 14%	-	2 11%
E43 Endocrinology (A561)	126 9%	13 8%	-	-
E44 Toxicology (A562)	129 9%	14 9%	-	-
E45 Urinalysis (A563)	322 23%	33 21%	-	2 11%
E46 Immunohematology (A564)	195 14%	20 13%	-	1 6%
E47 ABO Grouping/RH Typing (A565)	253 18%	23 14%	-	1 6%
E48 Atypical Antibody (A566)	176 12%	13 8%	-	-
E49 Compatibility Testing (A567)	229 16%	18 4%	-	-
E50 Hematology (A568)	259 18%	24 15%	-	2 11%
E51 Radiobioassay (A569)	8 1%	-	-	-
E52 Exfoliative Cytology (A570)	6*	-	-	-
E53 Histopathology (A571)	1*	-	-	-
E51 Oral Pathology (A572)	4*	-	-	-

* - Less Than 1%.

Chart No. 100 6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region VI	AR	NM
Facility Total	1416	301	37	17
E34 Bacteriology (A552)	210 15%	32 11%	6 16%	3 18%
E35 Mycobacteriology (A553)	72 5%	15 5%	-	-
E36 Mycology (A554)	50 4%	7 2%	-	-
E37 Parasitology (A555)	106 7%	16 5%	4 11%	-
E38 Virology (A556)	31 2%	2 1%	1 3%	-
E39 Immunology (A557)	84 6%	23 8%	5 14%	1 6%
E40 Syphilis Serology (A558)	144 10%	35 12%	4 11%	3 6%
E41 Non Syphilis Serology (A559)	252 18%	48 16%	9 24%	5 29%
E42 Chemistry (A560)	268 19%	37 12%	9 24%	3 18%
E43 Endocrinology (A561)	126 9%	28 9%	4 11%	-
E44 Toxicology (A562)	129 9%	23 8%	3 8%	-
E45 Urinalysis (A563)	322 23%	53 18%	11 30%	3 18%
E46 Immunohematology (A564)	195 14%	34 11%	9 24%	2 12%
E47 ABO Grouping/RH Typing (A565)	253 18%	49 16%	9 24%	3 18%
E48 Atypical Antibody (A566)	176 12%	27 9%	9 24%	2 12%
E49 Compatibility Testing (A567)	229 16%	36 12%	9 24%	3 18%
E50 Hematology (A568)	259 18%	37 12%	9 24%	3 18%
E51 Radiobioassay (A569)	8 1%	-	-	-
E52 Exfoliative Cytology (A570)	6*	3 1%	-	-
E53 Histopathology (A571)	1*	-	-	-
E51 Oral Pathology (A572)	4*	-	-	-

* - Less Than 1%.

Chart No. 101 6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region VII	Region VIII	Region IX
Facility Total	1416	228	178	88
E34 Bacteriology (A552)	210 15%	47 21%	58 33%	-
E35 Mycobacteriology (A553)	72 5%	-	23 13%	-
E36 Mycology (A554)	50 4%	-	19 11%	3 3%
E37 Parasitology (A555)	106 7%	2 1%	31 17%	4 5%
E38 Virology (A556)	31 2%	-	-	3 3%
E39 Immunology (A557)	84 6%	-	31 17%	3 3%
E40 Syphilis Serology (A558)	144 10%	10 4%	27 15%	2 2%
E41 Non Syphilis Serology (A559)	252 18%	60 26%	48 27%	1 1%
E42 Chemistry (A560)	268 19%	76 33%	47 26%	1 1%
E43 Endocrinology (A561)	126 9%	3 1%	48 27%	-
E44 Toxicology (A562)	129 9%	16 7%	48 27%	-
E45 Urinalysis (A563)	322 23%	71 31%	74 42%	-
E46 Immunohematology (A564)	195 14%	58 25%	41 23%	-
E47 ABO Grouping/RH Typing (A565)	253 18%	67 29%	43 24%	1 1%
E48 Atypical Antibody (A566)	176 12%	63 28%	28 16%	1 1%
E49 Compatibility Testing (A567)	229 16%	64 28%	36 20%	2 2%
E50 Hematology (A568)	259 18%	72 32%	48 27%	-
E51 Radiobioassay (A569)	8 1%	4 2%	-	-
E52 Exfoliative Cytology (A570)	6*	-	-	-
E53 Histopathology (A571)	1*	-	-	-
E51 Oral Pathology (A572)	4*	-	-	-

* - Less Than 1%.

Chart No. 102 6(b)

Laboratories in Non-Accredited Hospitals with Satisfactory Results in Proficiency Testing for Specific (Sub)Specialties

Deficiency	Nation	Region X	AK
Facility Total	1416	98	10
E34 Bacteriology (A552)	210 15%	13 13%	1 10%
E35 Mycobacteriology (A553)	72 5%	6 6%	-
E36 Mycology (A554)	50 4%	4 4%	-
E37 Parasitology (A555)	106 7%	12 12%	1 10%
E38 Virology (A556)	31 2%	6 6%	-
E39 Immunology (A557)	84 6%	10 10%	-
E40 Syphilis Serology (A558)	144 10%	7 7%	1 10%
E41 Non Syphilis Serology (A559)	252 18%	17 17%	1 10%
E42 Chemistry (A560)	268 19%	21 21%	1 10%
E43 Endocrinology (A561)	126 9%	5 5%	1 10%
E44 Toxicology (A562)	129 9%	7 7%	1 10%
E45 Urinalysis (A563)	322 23%	19 19%	1 10%
E46 Immunohematology (A564)	195 14%	9 9%	1 10%
E47 ABO Grouping/RH Typing (A565)	253 18%	17 17%	1 10%
E48 Atypical Antibody (A566)	176 12%	14 14%	1 10%
E49 Compatibility Testing (A567)	229 16%	24 24%	1 10%
E50 Hematology (A568)	259 18%	16 16%	1 10%
E51 Radiobioassay (A569)	8 1%	-	-
E52 Exfoliative Cytology (A570)	6*	-	-
E53 Histopathology (A571)	1*	-	-
E51 Oral Pathology (A572)	4*	-	-

* - Less Than 1%.

(c) Q Does HCFA routinely collect any other proficiency testing data for Medicare-certified labs or CLIA labs? If so, please provide summary data indicating lab performance by regions and nationally for the most recent year.

(c) A HCFA does not routinely collect any other proficiency testing (PT) data for Medicare certified laboratories or CLIA licensed laboratories. State survey agencies are sent copies of a laboratory's performance by the PT testing service (See below).

(d) Q What sanctions and timetables apply to a Medicare-certified lab that has unacceptable results in a proficiency test? How often have these been applied over the last five years? Can a lab that fails the proficiency test for a particular test still perform that test on a non-Medicare interstate or interstate basis?

(d) A Unsuccessful participation in PT is defined as three consecutive or three unsatisfactory overall results for a specialty or subspecialty in four consecutive shipments. Shipments of PT samples to the laboratory are on a quarterly basis.

The State survey agencies (SAs) monitor PT performance by reviewing each laboratory's PT shipment or survey performance report on a quarterly basis. These performance reports are sent to the SA directly from the PT program provider.

No action is taken other than possible consultation by the SA with the laboratory for the first occurrence of an unsatisfactory result by the laboratory for a specialty or subspecialty. The second occurrence of an unsatisfactory result reported for a specialty or subspecialty (two consecutive failures or two failures in three consecutive shipments) results in the State agency notification (warning letter) to the laboratory by certified mail that significant performance problems exist, and that if unsatisfactory results continue to be reported, Medicare approval to provide services in the deficient specialty or subspecialty may be withdrawn. At the third occurrence of an unsatisfactory result, the SA notifies the laboratory by certified mail that a recommendation will be made to the regional office to terminate the laboratory's approval in the specialty/subspecialty in question.

Since 1980, 61 independent laboratories have been terminated from Medicare because the condition of proficiency testing was found to be out of compliance. However, these laboratories also may have had additional conditions out of compliance at the time of termination.

We do not have data on the number of warning letters sent to laboratories informing them of their unsatisfactory performance in PT by our SAs.

A laboratory that fails proficiency testing for a particular test can still perform that test on a Medicare and a non-Medicare interstate basis because Medicare does not terminate a laboratory's approval by test but terminates approval by laboratory specialty or subspecialty. However, if a laboratory is only certified to perform one test under a specialty or subspecialty and fails proficiency testing for that test, the laboratory can be terminated for that specialty or subspecialty. But if the laboratory is certified to perform many tests under a specialty or subspecialty, failing proficiency testing for one of those tests will not cause the entire specialty or subspecialty to be terminated. For a laboratory that participates in Medicare and is also licensed under CLIA, the interstate license could be limited to exclude testing for a particular test but a similar action could not be taken under Medicare.

(e) Q What sanctions and timetables apply to a lab in a hospital deemed to be Medicare-certified through the Joint Commission if such a lab fails a proficiency test? How often have these been applied in the last five years?

(e) A We do not routinely monitor the proficiency testing performance of laboratories in Joint Commission accredited hospitals. However, if the condition of laboratory services is found to be out of compliance because of problems found in proficiency testing during a scheduled validation survey or a complaint investigation by our State agency, the hospital can be placed under State agency monitoring. See response to question 5(b), for the number of Joint Commission hospitals placed under State agency monitoring because the condition of laboratory services was not met. Many of these hospital laboratories were found to have problems in the area of proficiency testing.

(f) Q What sanctions and timetables apply to a CLIA lab that has failed a proficiency test? How often have these been applied over the last five years? Can a lab that fails the proficiency test for a particular test still receive Medicare payment for that test or perform it on an interstate basis?

(f) A A CLIA laboratory's license may be revoked in total or limited by individual tests/procedures or by specialties/subspecialties for failures in proficiency testing. However, before an adverse action is taken to revoke or limit a license, the CLIA statute requires that the laboratory must be given a notice proposing to take such action and offering an opportunity for a hearing. The CLIA license cannot be revoked or limited pending the outcome of the hearing by an Administrative Law Judge. This process from time of notice to date of hearing can take up to 120 days. Since September, 1986, when CDC stopped offering a proficiency testing program, no CLIA adverse actions have been processed based solely on unsatisfactory proficiency testing performance because the grading system specified under CLIA does not correlate with grading systems used by any proficiency testing program other than that formerly operated by CDC. This situation will be resolved by a uniform proficiency testing program which will be included in the proposed laboratory regulations.

Chart No. 85 lists the number of adverse actions taken against CLIA laboratories for failures in proficiency testing for the past five years.

Since many CLIA laboratories are also Medicare approved, a proficiency testing failure for CLIA may cause Medicare termination in a specialty or subspecialty. However, proficiency testing failure for an individual test may not always cause Medicare termination of payment for individual tests in a specialty or subspecialty.

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Care Financing Administration

Washington, D.C. 20201

APR 22 1988

The Honorable William S. Cohen
United States Senate
Washington, D.C. 20510

Dear Senator Cohen:

As dicussed with staff members of the Subcommittee on Oversight of Government Management, we are forwarding responses to four of the questions posed in your letter of April 7. As agreed, the remaining responses will be forwarded on May 4.

Please let me know if I can provide any additional information on the material enclosed in this letter.

Louis B Hays

Louis B. Hays
Associate Administrator for Operations

Enclosure

Personnel Standards

1. Q. We heard much testimony about the necessity of having qualified personnel performing lab tests to assure the quality of those tests. At the same time, we heard testimony that HCFA is planning to relax the current personnel requirements for independent laboratories. **What is HCFA's position on the need for personnel standards for people working in labs, including physician office labs?** What is HCFA's view on allowing people who demonstrate proficiency through an examination, but do not have the required educational credentials, to work in a lab or even direct a lab?

A. HCFA favors laboratory standards that will improve outcome measures of performance and assure that personnel requirements reflect the state-of-the-art in laboratory science. Furthermore, **we will propose strenthened quality assurance standards which, among other things, will assure that personnel are performing properly regardless of their paper credentials.** HCFA has not yet made a decision on the health and safety standards, including personnel standards, that it will require of physicians' office laboratories that perform more than 5,000 tests annually (section 4064 of the Omnibus Budget Reconciliation Act of 1987). HCFA would not support the resumption of proficiency examinations for laboratory directors or staff as a substitute for their meeting existing Federal educational requirements to work in or even direct a certified clinical laboratory.

HCFA's independent laboratory regulations once included a provision which allowed a person to qualify as a laboratory director by passing a proficiency examination. This provision was a part of a "grandfather clause" and its intent was to assure that individuals working in laboratories in 1968, when the regulations were implemented, were not regulated out of a job. The provision expired June 30, 1971 and HCFA has no plans to resurrect it because the temporary "grandfather clause" resolved the issue of equity for individuals who served as laboratory directors before the Federal requirements were established.

Section 1123 of the Social Security Act contained a provision for offering proficiency examinations to, among others, laboratory technologists. The examination was given seven times. However, the statutory authority to offer it again expired September 30, 1987.

Enforcement and Adverse Actions

1. Q. Under CLIA, HCFA has authority to enjoin a lab from performing tests in interstate commerce and to levy fines against lab owners and operators. Have these authorities ever been used? Please provide examples of what would constitute grounds for an injunction against a licensed lab for a fine or imprisonment.

A. The CLIA provision dealing with an injunction against a laboratory is separate and distinct from the provision relating to fining and imprisoning a laboratory owner or operator, and one does not necessarily have anything to do with the other.

An injunction under Section 353(f) of CLIA involves bringing a suit against a laboratory in United States District Court, based upon a belief that it is engaged in an activity that represents an imminent hazard to the public health. **HCFA has recommended an injunction** on one **occasion. An example of such an activity would be reporting out test results, but not actually performing the tests ("sink testing").**

Section 353(h), the section of CLIA that speaks to fining and imprisoning a person who willfully violates the CLIA statute and regulations, is not an action that HCFA directly undertakes. If HCFA has evidence that indicates a laboratory has willfully violated provisions of CLIA, it refers the case to the Office of the Inspector General (OIG) for any action it may wish to take. **HCFA has referred twelve such cases to the Inspector General's office, and is aware of one instance in which a fine** was **imposed against the laboratory owner or operator.** Examples of cases that are referred to the OIG include those in which HCFA has evidence of **testing specimens** in **interstate commerce without a CLIA license and obtaining** a **CLIA license through misrepresentation of required information.**

Cytology Services

2. Q. How many labs are certified under Medicare or licensed under CLIA to perform cytology services? How many State surveyors, HCFA regional office staff, and HCFA central office staff are certified cytotechnologists, cytopathologists, or pathologists?

A. There are 1,244 independent laboratories that are approved for Medicare participation in cytology. HCFA has no data on the number of Medicare approved hospitals that perform cytology testing. There are 486 laboratories licensed under CLIA to perform cytology testing.

Two State agency surveyors are licensed cytotechnologists and 1 State agency surveyor is a licensed pathologist. One HCFA regional office laboratory employee is a licensed cytotechnologist. There are no cytopathologists who are State agency or HCFA regional office employees. HCFA's central office has no employees who are licensed cytotechnologists, cytopathologists or pathologists.

Physician Office Labs

1. Q. HCFA testimony stated that the congressionally mandated study of POLs, due in 1986, will be released "soon." What is the current schedule for releasing this study? How does HCFA plan to identify physician offices performing tests? How does HCFA plan to identify POLs that pass the 5,000 test threshold? Do you interpret this 5,000 threshold as counting only Medicare-reimbursed tests? How does HCFA plan to take action against POLs -- by specialty and subspecialty or some other way?

   A. The Report to Congress on Physicians' Office Laboratory is currently under review in the Department. Once that review is completed, it will be forwarded to the Office of Management and Budget. We are evaluating various methods for identifying physicians who perform more than 5,000 tests annually. HCFA has not made a decision at this point concerning either the including of non-Medicare specimens in the 5,000 count, or how it will take action against physicians' office laboratories. We fully expect to meet the statutory effective date of January 1, 1990.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Washington, D.C. 20201

JUN 2 1988

The Honorable William S. Cohen
United States Senate
Washington, D.C. 20510

Dear Senator Cohen:

Thank you for your letter of April 7, 1988 requesting information on the issue of quality in clinical laboratories approved for participation in the Medicare program and licensed under the Clinical Laboratory Improvement Act (CLIA). I regret that my response has been delayed.

Enclosed is our response to your specific questions. However, please note that certain material requested in your letter was forwarded to you on April 22, 1988, and is not included in this package.

Please let me know if I can provide any further assistance to you.

Sincerely,

Louis B. Hays
Associate Administrator for
Operations

Enclosure

RESPONSES TO INFORMATION REQUESTED

Cytology Services

Q. Do State surveyors who perform inspections under contract with HCFA receive training in cytology? Does training vary from region to region? Does HCFA have plans to improve the surveyor competence in cytology practices?

A. HCFA has both a basic and advanced laboratory training course that all State agency surveyors who inspect laboratories must attend. Specialized training in surveying laboratories that perform cytology testing is conducted by a HCFA staff member who is a cytotechnologist with experience working in cytology in a clinical laboratory. HCFA will expand its training program to improve surveyor competence in inspecting cytology laboratories. The expanded program will include the use of audio visuals, video tapes and "hands-on" and "through the microscope training" for laboratorians surveying cytology laboratories.

Q. In total dollars, how much does Medicare reimburse for Pap smear testing in physician office laboratories? Does most of this reimbursement go to gynecology offices? Are there restrictions on Medicare reimbursement for Pap smears?

A. According to information obtained from 1986 BMAD data, Medicare paid approximately $5.3 million for Pap smear testing. Of this amount, about $2.3 million was paid for diagnostic services in physicians' offices. (Under the Deficit Reduction Act of 1984 physicians may bill for laboratory services only when they personally perform for supervise the test). Of the $2.3 million, the specialty of gynecology receives reimbursement of approximately $850,000, the largest reimbursement to a physician specialty group for this test.

Medicare reimbursement for a Pap smear can be made if there is an appropriate physical condition that supports the test. Routine tests are not covered under Medicare.

Q. How long has HCFA been examining contracting out for review of previously read cytology slides? When do you expect the contract mentioned in your testimony to be awarded? When do you expect the review to be completed? What will this review accomplish besides being a one-time review of selected laboratories performing cytology services?

A. HCFA began examining contracting out for the review of previously read cytology slides in February 1987. This contract will be awarded before September 30, 1988, and will be completed one year after it is awarded. The reports produced by the contractor will enable us to identify problem areas that will be addressed in revisions of surveyor training, instructive guidelines, and, if necessary, regulations.

The contractor will make onsite inspections of cytology laboratories and perform examinations of previously reported slide preparations. If discrepancies exist between contractor findings and laboratory results, the contractor will perform an offsite review of a larger sample of the previously reported cases. We will request plans of correction for identified deficiencies and, if necessary, terminate laboratories that have serious problems in cytology testing.

We will also extend this monitoring process on an indefinite basis if serious deficiencies are identified by the contractor in laboratories selected for cytology slide review.

Q. Has HCFA looked into establishing a cooperative agreement with the Armed Forces Institute of Pathology in the area of cytology rescreening? What decision was reached and what was the basis for that decision?

A. HCFA has discussed the possibility of specialized training for State agency surveyors of cytology laboratories with staff of the Armed Forces Institute of Pathology (The Institute). The Institute is willing to provide an in-depth training course for State agency surveyors of cytology laboratories at regular intervals throughout the year. The Institute also indicated an interest in providing pathologists to assist HCFA in conducting onsite cytology reviews. We are in the process of finalizing arrangements with the Institute.

HCFA Inspections

1. Q. Charges were made during the hearing that the inspection process under Medicare is uneven from State to State, that it focuses on paperwork instead of quality control, and that inspectors, particularly when surveying cytology services in a lab, often do not have the required expertise to inspect the lab. What assurance does HCFA have that the States are adequately enforcing the Medicare and CLIA standards?

A. All State survey agencies are provided the same statutes, regulations, regulatory interpretive guidelines, certification instructions, policies and training concerning the Medicare/CLIA inspection process. Laboratory inspections are performed by laboratorians (technologists or microbiologists) who receive training from both the HCFA central and regional offices, and all of our training efforts are devoted to the uniform application of Medicare standards. It is true that the State survey agencies have only a few cytotechnologists, cytopathologists, or pathologists to inspect cytology laboratories. However, all surveyors who inspect cytology laboratories receive specialized training conducted by a HCFA staff member who is cytotechnologist with bench experience in cytology.

In addition, as we indicated in our response to the first question, HCFA will expand its training program to improve surveyor competence in inspecting cytology laboratories. The expanded program will include the use of audio visuals, video tapes and "hands on" and "through the microscope training" for laboratorians surveying cytology laboratories.

Although current Medicare regulations and interpretive guidelines contain many requirements related to personnel and administrative matters, the bulk of the regulations and interpretive guidelines are very detailed and prescriptive and focus on the specific measurement of laboratory performance. For example the guidelines contain 28 pages of instruction devoted to quality control practices and an additional 85 pages that address blood banking safety. Moreover, based on survey data that we provided you, numerous deficiencies are cited to laboratories by the State survey agencies, and we receive many complaints that our requirements and their application are too stringent.

HCFA regional offices monitor the performance of State survey agencies to assure that States enforce Medicare and CLIA standards by conducting comparative surveys of a sample of laboratories inspected by the States and by making periodic reviews of the State agencies to assure that State agencies adhere to Medicare policies and guidelines.

2. Q. With regard to the monitoring inspections HCFA performs to review the State agencies, according to information HCFA provided, a vary small sample of labs is included (about one percent of the labs that the States survey), and prior to this year HCFA could not make national projections about State surveyor performance, based on the method of sample selection. Does HCFA consider this number of labs surveyed adequate to make a reliable assessment of State performance? Given the nature of the sample for the monitoring surveys prior to 1988, and the fact that only two-thirds of the surveys (61 of 89) were actually keyed into HCFA's central data system for 1987, is it correct to report 98 percent agreement between Federal and State surveys, implying a very high level of agreement nationwide.

A. A one percent sample is ordinarily a small sample for achieving statistical reliability. However, there are other considerations. The Federal monitoring survey (FMS) program transcends State and (HCFA) regional lines, and the surveys were conducted by different surveyors from each of HCFA's 10 regional offices. Despite the size of the sample, the 98 percent agreement between Federal and State surveys confirms a high level of agreement nationwide.

Nationally, for the 61 FMS laboratory surveys conducted during FY 1987 there was 98 percent agreement with State deficiency findings at the condition level, 97 percent at the standard level, and 98 percent at the element level. HCFA did not include the 28 monitoring surveys conducted during FY 1987 for which it has no data for arriving at the level of agreement.

For FY 1988, specific regional monitoring survey targets were derived from a national statistical sample. To ensure the validity and integrity of the sample, an unbiased and random sample listing of labs was provided to the regional offices. Approximately 164 FMS laboratory surveys will be conducted in FY 1988.

3. Q. We have heard reports that some States do not follow the HCFA guidelines that lab inspections must be unannounced. What assurance does HCFA have that all states are performing unannounced inspections?

A. HCFA's regional offices monitor State survey agencies to assure that they follow HCFA's policies, guidelines and instructions. Any deviations from HCFA's policies, including our policy of unannounced visits for independent and CLIA laboratories, is brought to the attention of the management of the State survey agency for corrective action. To the best of our knowledge, the laboratory surveys being performed by State agencies are unannounced. We would appreciate receiving any information that the committee may have about specific violations of the long-standing policy of unannounced surveys.

4. Q. We have also heard complaints that State inspectors do not check activity on the night and "graveyard" shifts in large 24-hour labs where the bulk of the work is performed overnight. Does HCFA have a requirement to make inspections during this time period?

A. HCFA survey procedures do not require that laboratories be surveyed at night or during "graveyard" shifts. However, a number of State survey agencies have indicated that they do conduct inspections during these hours.

5. Q. HCFA data indicate that one in three labs (32 percent) were not performing an important quality control function designed to assure that the daily results the lab is reporting on patients tests are accurate. If an inspector finds that lab is not running daily quality control checks and keeping records of the results and their actions taken based on those checks, is this sufficient grounds for action against a lab? Why isn't more weight given to this particular survey finding?

A. We assume you are referring to deficiencies cited under 42 CFR 405.1317(a)(1), the Quality Control Condition. This regulation states "Quality controls imposed and practiced by the laboratory must provide and assure: preventive maintenance, periodic inspection, and testing for proper operation of equipment and instruments as may be appropriate; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial action to be taken in response to detected defects."

In your example, if an inspector finds that the laboratory is not running daily quality control checks and keeping records of the results and their actions taken based on those checks, this would indeed be grounds for action against the laboratory.

HCFA does give great weight to deficiencies identified under this part of the regulation. We encourage State survey agencies to cite all deficiencies in quality control no matter how minor, so that the laboratory is made aware of them and can then make the necessary corrections of these deficiencies.

However, it must also be noted that many of the deficiencies identified in this requirement are minor deficiencies that are easily corrected. For example, a survey finding that a laboratory was using one expired reagent would not provide a sufficient basis for termination of the laboratory's participation in Medicare, although such a finding would constitute a deficiency (requiring corrective action) under 42 CFR 405.1317(a)(1).

6. Q. HCFA found a similar incidence of this sort of quality control problem (about 39 percent of the labs) in 1980. Has HCFA taken steps to improve the performance of quality control since this time?

A. HCFA is always attempting to improve quality control performance in clinical laboratories. Specifically, since 1980 we have:

- o Sought the recommendations of the Centers for Disease Control and the Food and Drug Administration to develop revisions to our quality control guidelines;
- o Initiated contacts with groups and organizations outside the Federal government to develop revisions to our quality control guidelines that reflect changes in laboratory technology that are permissible within the scope of the regulations. These groups include Health Instrument Manufacturer's Association, National Council for Health Laboratory Services and the National Committee for Clinical Laboratory Standards; and
- o Revised the surveyor guidelines affecting quality control based on the results of these meetings and discussions and highlighted the changes at our surveyor training courses.

Our revisions to the clinical laboratory regulations will reflect current laboratory practices, including those related to quality control.

Enforcement and Adverse Actions

2. Q. Does HCFA plan to extend intermediate sanctions to CLIA laboratories or POLs? If you do not believe you currently have the legislative authority to apply the sanctions to non-Medicare laboratories, would legislation giving you such authority improve your capability to act against these laboratories?

A. The Omnibus Budget Reconciliation Act of 1987 did not authorize HCFA to apply intermediate sanctions against CLIA laboratories. However, under the existing CLIA statute, HCFA is able to revoke, limit, or suspend CLIA licenses in whole or in part. Also, the CLIA statute permits the imprisoning of laboratory owners or operators who willfully violate the CLIA statute or regulations.

At this time, HCFA has not made any decisions on how intermediate sanctions will be applied against physicians' office laboratories.

3. Q. How will HCFA apply the intermediate sanctions in deemed status institutions, particularly Joint Commission accredited hospitals? Does HCFA currently have access to the performance information from the Joint Commission that would be necessary to apply such sanctions?

A. Application of intermediate sanctions in an accredited hospital would be preceded by suspension of the hospital's deemed status. Throughout the year, State survey agencies conduct validation surveys and complaint investigation surveys in hospitals accredited by the Joint Commission. When a State agency survey identifies significant deficiencies in a hospital's performance, the hospital is placed under the State agency's surveillance until the deficiencies are corrected. If the deficiencies are not corrected, the State survey agency will then recommend that HCFA either apply intermediate sanctions, or if the circumstances warrant, terminate the hospital's participation in the Medicare and Medicaid programs.

HCFA does not have current access to the results of JCAHO accreditation surveys. However, the Joint Commission has been asked to work with HCFA staff to arrange for the release of data that will:

- Identify hospitals and hospital laboratories that are accredited with one or more deficiency; and
- Summarize deficiency data derived from accreditation surveys of hospitals and hospital laboratories.

That information is essential to the application of intermediate sanctions.

Proficiency Testing for Enforcement Purposes

1. Q. With the absence of a national PT grading system under Medicare, is any action being taken against labs on poor PT results?

A. Despite the current lack of a national PT grading system, action is being taken against laboratories because of poor PT results. To determine compliance with Medicare requirements, State survey agencies employ their own grading system or use the grading system developed by PT providers.

New Hampshire, West Virginia, Delaware, Ohio, Indiana, Texas, New Mexico, Arkansas, Oklahoma and Nevada use the grading system developed by the PT providers. The other States apply their own grading system to the PT results.

2. Q. If a lab continually fails PT on an individual test like bilirubin, will it continue to be paid for that test under Medicare?

A. Independent laboratories that continually fail proficiency testing (PT) on an individual test such as bilirubin will continue to be paid for that test under Medicare, because Medicare regulates independent laboratories by groups of test (specialties and subspecialties) rather than by individual tests. PT providers include bilirubin in their chemistry PT program as but one test of approximately 20 tests that comprise the particular chemistry subspecialty, and all of these tests are separately graded. We can discontinue payment for bacteriology, mycology, parasitology and virology based on a laboratory's unsatisfactory PT performance because these tests are regarded as specialties or subspecialties. Also, Section 4064 of the Omnibus Budget Reconciliation Act of 1987 allows intermediate sanctions to be imposed against providers or clinical laboratories effective January 1, 1990. The sanctions permitted under Section 1846 include suspension of payment for all or a part of a facility's clinical laboratory tests.

3. Q. Which States are taking action under Medicare or CLIA by applying their own individual grading system to proficiency testing results? What is happening in States that have not taken this initiative?

A. No action is currently being taking against CLIA laboratories with respect to proficiency testing results, because CDC discontinued its proficiency testing program and no new program for CLIA laboratories has been established by HHS. HCFA plans to propose a new proficiency testing program for both Medicare and CLIA laboratories as part of the proposed revision of the clinical laboratory regulations.

With respect to the Medicare program (including Medicare labs also licensed as CLIA labs), the following States apply the grading criteria developed by the PT providers to determine compliance with Medicare PT requirements: New Hampshire, West Virginia, Delaware, Ohio, Indiana, Texas, New Mexico, Arkansas, Oklahoma and Nevada. The other States apply their own grading system to the PT results.

4. Q. For labs licensed under CLIA in 1986, according to data HCFA provided, 23 percent have had their license revoked for a test or category of testing over the last six years for flunking PT. Now that CDC is out of the PT business, HCFA can no longer take such actions against labs. Does HCFA view this as impeding efforts to ensure lab quality?

A. We do not view the program's demise as impeding efforts to ensure laboratory quality because most CLIA laboratories also participate in the Medicare program and they must continue to be enrolled in a PT program to meet Medicare requirements.

Also, although we cannot revoke, limit, or suspend CLIA licenses based on PT failures, we directed all CLIA licensed laboratories to enroll in either the College of American Pathologists' or the American Association of Bioanalysts' PT program. Responses to a followup questionnaire confirmed that of 1,514 licensed laboratories, 1,437 had joined one of the approved PT programs. We advised the remaining 77 laboratories that failure to participate in an approved PT program would result in the loss of their CLIA license.

The CLIA laboratories' participation in the approved programs will serve to buttress the quality of their performance until the uniform PT program that we are proposing in our revised clinical laboratory regulation becomes effective.

5. Q. CLIA has been in force since 1967, yet some States still have little or no regulation of labs. Should the Federal presence in lab testing quality assurance be extended to non-Medicare intrastate labs?

A. HCFA does not believe the institution of a Federal laboratory standards enforcement program to replace State regulation of intrastate labs is necessary. The State personnel that perform surveys for Medicare usually review these labs. Improvements in State regulation of clinical laboratories have already been achieved without the expansion of the Federal role in standards enforcement by:

- Medicare training programs for State laboratory surveyors; and
- Voluntary State substitution of Federal clinical laboratory requirements for less stringent State requirements.

Validation of Deemed Organizations

1. Q. What does HCFA do to validate the CAP accreditation process under CLIA? Does HCFA validate the CAP process through inspections of its own, similar to the validation surveys performed of Joint Commission Hospitals?

   A. HCFA has not established a special system for monitoring CAP-exempted laboratories. However, State survey agencies inspect a sample of the 2,500 CAP accredited laboratories in accredited hospitals as part of HCFA's overall validation of JCAHO inspection practices.

   In addition, in 1986 we reviewed the Medicare survey data on the 200 CAP accredited independent laboratories. That review confirmed that all 200 CAP laboratories were in compliance with Medicare/Medicaid requirements.

2. Q. When was the last time that HCFA evaluated CAP's standards to determine whether they continue to be equal to or more stringent than the HCFA requirements?

   A. HCFA last evaluated CAP's standards to determine whether they continue to be equal to or more stringent than HCFA requirements in September 1987.

   However, HCFA is in the process of revising its lab regulations. When the revised regulations become final, we will again review the comparability of Medicare requirements.

3. Q. Has HCFA established guidelines or criteria that will be used to determine whether a private sector entity should be granted deemed status under Medicare?

A. Shortly after the passage of the Deficit Reduction Act of 1984, HCFA established the following criteria which have been used to evaluate requests for recognition of private accreditation programs:

- o The adequacy of the organization's survey process; for example, the frequency of surveys and the composition of the survey teams;
- o The adequacy of the accrediting organization's enforcement and monitoring procedures;
- o The equivalency of the accrediting organization's standards to Medicare's conditions of participation; and
- o The availability and validity of the data to be submitted to enable HCFA to monitor the performance of the accrediting organization and to compare the results of accreditation inspections with Medicare survey findings.

4. Q. As a result of the surveys HCFA performed in 1986 for validating the Joint Commission, HCFA found it necessary to place eight percent of the hospitals under State agency monitoring because "the condition of laboratory services was found to be out of compliance." By our calculation, based on the sample size and the eight percent finding, the actual number of Joint Commission hospitals with labs out of compliance with the Medicare conditions of participation could be as high as 16 percent (one in six hospitals). If, in such a small sample of hospitals, HCFA found it had to take action in eight percent of the cases where the Joint Commission had already certified the hospital (including the lab), does this suggest to you that there may be a problem with the population of Joint Commission hospitals?

A. We provided you with information that in 1986 HCFA conducted validation surveys on 48 of the 5,100 Joint Commission hospitals, and found that four of the 48 (8 percent) were not in compliance with the laboratory condition requirement. Our extrapolated calculation, based on the universe of 5,100 hospitals and the 8 percent deficiency finding, is that 408 hospitals (1 in 12) would have laboratory problems if we validated 100 percent of the Joint Commission's findings.

However, we agree that we should increase our ability to identify problems in the entire population of accredited hospitals. We have asked the Joint Commission to work with us to provide summary deficiency data on all accredited hospitals and hospitals laboratories. This data will enable HCFA to compare Medicare survey findings with the results of all accreditation surveys.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

MAY 5 1988

The Honorable William S. Cohen
Ranking Minority Member
Subcommittee on Oversight of Government
  Management
Committee on Government Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Senator Cohen:

This is in response to your letter dated April 14 submitting several questions for response in followup to my testimony on March 24 before the Subcommittee on Oversight of Government Management. Responses to these questions are enclosed.

We appreciate your interest in the issue of quality in clinical laboratory testing and are pleased to provide assistance to the Subcommittee in examining this very important area.

Sincerely yours,

Paul J. Wiesner, M.D.
Director
Training and Laboratory Program Office

Enclosures

CENTERS FOR DISEASE CONTROL RESPONSES TO
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
FOLLOWUP TO MARCH 24 TESTIMONY OF DR. PAUL WIESNER

Uniform National Proficiency Testing Proposal

1. How were the overall grades (for example, 70 per cent in Chemistry) determined for CDC's proposed uniform proficiency testing system? What criteria were used?

The grading criteria were established after careful review of several considerations including:

(1) The grading of discrete test performance used in CLIA'67 was merged with the composite grading by specialty used by Medicare. This merger permits action to be taken against a laboratory that poorly performs either a specific test, such as calcium, or a category of tests, such as hematology.

(2) Criteria for acceptable laboratory performance are best established on the basis of the clinical usefulness of test results. However, there is no general agreement upon criteria for medical usefulness in most laboratory tests. Therefore, evaluations of performance must be made using the present state of the practice.

(3) The evaluation period is extended over three surveys so that a laboratory's failure in proficiency testing is a defensible indication that it is routinely providing poor quality laboratory results.

A cumulative composite score of at least 70% for all tests over three surveys must be maintained for the aggregate of all testing categories. However, 100% performance is required in blood banking, where errors may have serious immediate consequences. In addition, laboratories are not permitted to fail consistently any single test in two of three surveys. This scoring system should permit the detection of laboratories whose results are consistently marginal or worse, while not penalizing a laboratory that rarely produces marginal results.

Was there analysis of the impact of setting these grades at different levels?

An analysis was made of setting composite passing scores for laboratories at 70 to 90% using 1986 College of American Pathologists' survey data. For example, for the specialty of chemistry, 4.8% of 7,869 laboratories would fail the specialty of chemistry if the passing score was set at 70%, whereas more than 8% would fail using a 90% passing score. A preliminary analysis of hematology data showed that a 90% passing score would fail almost 34% of the participating laboratories, while a 70% score would fail 12% of laboratories. Since the laboratories that participate in the

College of American Pathologists' program are likely to represent some of the Nation's best laboratories, a higher failure rate is expected on application of this scoring system to all laboratories that are federally monitored.

How many labs would have failed in 1987 if the pass rate was 90 percent in all areas?

An analysis of all laboratories that would have failed during 1987 using a 90% passing score is not available at present. We are working with the College of American Pathologists and American Association of Bioanalysts data for 1987 to develop this information and will provide it to the Committee when it becomes available.

2. How difficult will it be to change the grading criteria for a particular test should advances in medical technology or practice make that necessary?

The Health Care Financing Administration is aware of the need to keep the proficiency testing requirements current. The intent is to keep the proficiency testing options as flexible as possible. Any changes in proficiency testing requirements would necessitate modifying those specific aspects of the regulations.

3. You testified that, "there should be proficiency testing whenever possible for almost all analytes used for clinical specimens." Why then is the CDC proficiency testing proposal limited in the number of analytes it covers?

Our recommendation to the Health Care Financing Administration was to require proficiency testing, if available from an approved proficiency testing provider, for all tests for which service is offered by a laboratory. Not all tests were included in the federally evaluated portion of proficiency testing because of concerns about obtaining suitable materials to evaluate performance or because of the lack of a professional consensus about what should be evaluated or how performance should be assessed. Nonetheless, we believe that participation in a proficiency testing program for all tests for which programs are available is an important part of a laboratory's own internal quality assurance and should be required as a tool for promoting laboratory quality. Proficiency testing in this latter context would be used for the purpose of education and improvement rather than to take a regulatory action based on unacceptable performance.

New or experimental tests will be added to proficiency testing programs and will be used for educational and improvement purposes until they are well defined and can be added to the regulatory portion of proficiency testing. Every attempt must be made to keep this entire process as dynamic as possible so that laboratories, the Federal government, and patients can benefit from the educational and regulatory aspects of proficiency testing.

Monitoring the Performance of the CAP Under CLIA

1. I understand that, prior to the Memorandum of Understanding in 1987 between HCFA and CDC, CDC had the responsibility to validate the performance of CAP under CLIA. What has CDC done in the past to validate the CAP inspection and accreditation process? Has CDC ever surveyed a sample of CAP-accredited labs for the purpose of validating the CAP? Please provide documentation of any assessment CDC has made of the CAP inspection and accreditation process under CLIA.

For 11 of the 15 years between 1972 and 1986, CDC inspected roughly 10% of the approximately 150 CLIA laboratories enrolled in the College of American Pathologists' inspection and accreditation program. In addition, CDC reviewed the College of American Pathologists' proficiency testing program to determine whether the program was equal to or more stringent than the CDC proficiency testing program of the previous year.

An example of CDC inspection findings to validate a College of American Pathologists' inspection is provided in the enclosure. CDC examined 14 laboratories approximately 3 months subsequent to a College of American Pathologists' inspection. The CDC examiner reviewed the deficiencies found by the College of American Pathologists during its inspection and determined whether these deficiencies had been corrected. In addition, any other deficiency was noted. Only five uncorrected deficiencies were found. Although more total deficiencies were found by CDC, the College of American Pathologists' inspection found more deficiencies in 8 of the 14 individual categories examined. The College of American Pathologists and CDC laboratory inspection checklists contained the same general categories, although the level of detail within categories varied; however, the College of American Pathologists' inspection process was considered to be equivalent to the CDC process.

Cytology Proficiency Testing

1. Has CDC made any assessment of the application of videodisc technology to the problem of duplicate samples for proficiency testing in cytology, as suggested by a representative of the American Society of Cytotechnologists at the hearings?

CDC has not assessed the application of videodisc technology as a means of proficiency testing. The topic was discussed at a March 1-2, 1988, Conference of the State-of-the-Art in Quality Control Measures for Diagnostic Cytology Laboratories sponsored by CDC, National Institutes of Health, and Health Care Financing Administration. This method warrants further investigation.

2. You testified that CDC believes it "will be able to come up with a consensus on the scientific application of a proficiency testing program for cytology." How long will the development of this consensus take? One month? One year? Five years?

The conference on March 1 and 2 brought together about 150 individuals to discuss performance standards for cytology laboratories, including proficiency testing. The purpose of this conference was to initiate discussion of the broad range of issues related to Pap smear screening and to have these individuals solicit comments on this area at their organizational meetings (such as the American Society of Cytotechnologists and College of American Pathologists) this spring. As soon as these meetings are over and the societies have dealt with the issues, we will meet with representatives of the relevant societies to discuss further the development of standards for Pap smear screening, including proficiency testing. We anticipate providing final recommended standards to the Health Care Financing Administration by September 30, 1988.

1985
SUMMARY OF EXAMINATIONS
14 LABORATORIES

CATEGORY	CAP DEFICIENCIES	CDC DEFICIENCIES	UNCORRECTED DEFICIENCIES
GENERAL	2		
MICROBIOLOGY AND SEROLOGY			
Bacteriology	22	44	3
Mycology	5	10	
Parasitology	12	7	
Syphilis Serology	7	8	
Non Syphilis Serology	7	4	
CLINICAL CHEMISTRY			
Blood and CSF	14	33	1
Toxicology	1	2	
Urinalysis	11	3	
IMMUNOHEMATOLOGY	11	2	
HEMATOLOGY	14	15	
PATHOLOGY			
Cytology	7	6	1
Histology	8	4	
RADIOBIOASSAY	2	1	
TOTAL DEFICIENCIES	123	139	5

College of
American
Pathologists 5202 OLD ORCHARD ROAD SKOKIE ILLINOIS 60077-1034 (312) 966-5700

April 22, 1988

The Honorable William S. Cohen
Ranking Minority Member
Subcommittee on Oversight of Government
  Management
Committee on Governmental Affairs
United States Senate
Washington, DC 10510

Dear Senator Cohen:

The College of American Pathologists (CAP) is pleased to respond to your April 7, 1988, request for information regarding the CAP's Laboratory Improvement Programs. For the sake of simplicity, we will repeat your questions in the same order submitted, followed by our responses.

The CAP Inspections and Training

(1) Please describe the CAP training program for inspectors that was mentioned in testimony. How long does the program last? What topics are covered? How often must inspectors attend? Does the whole team have to participate in this training or is it only required of the pathologist-leader of the inspection team?

CAP Response:

The Commission on Laboratory Accreditation (CLA) conducts two or three one-day regional inspector training sessions annually in conjunction with its scheduled meetings. These training sessions are open to current inspectors, prospective inspectors, and team members. From 75 to 125 individuals attend each of these sessions. Presented by members of the Commission, these programs usually are formatted to provide an update on changes in the program and new program initiatives. The Commission attempts to schedule meetings so each region can host such a meeting at least once each three to four years. Sample agendas from recent training sessions are included in Appendix 1.

In addition to the regional training sessions, a core training program including slides with accompanying script and other support materials are available for loan to any region or local group of inspectors who wish to conduct an inspector workshop. These materials are updated continually as needed to reflect changes in the program. Workshops usually are conducted the day preceding an actual inspection. Thus the trainees can immediately follow up the didactic instruction with direct experience. All such programs are conducted by experienced inspectors.

Although there is no requirement as to frequency of re-training, new inspectors must participate in one of the training activities or serve as a team member on an inspection before they can lead an inspection. All inspectors in a region are invited and encouraged to attend the regional seminars when they are in their area. **Only team leaders are required to have completed a formal training activity.** However, team members are welcome to participate.

(2) In 1987, in how many inspections did each CAP inspector participate? Does the CAP have a policy regarding a number of inspections in which each inspector must participate?

CAP Response:

We do not maintain records on frequency of inspections per inspector except for the inspection team leaders. Based on a sampling of inspections conducted in 1987, the average number of inspections conducted per team leader was 1.56. The frequency distribution is as follows:

# of Inspections Performed/Team Leader	% of Inspectors Performing Specified Number
1	71.4 %
2	17.6 %
3	5.8 %
4 or more	5.2 %

The CAP does not have any requirement regarding the number of inspections in which each inspector must participate.

(3) How are the CAP inspection teams put together? Does the pathologist-leader of the team usually take employees from his or her own laboratory, or are teams put together from different labs? If the pathologist takes employees from his or her own lab, how conducive is this to objectivity on the part of the team members?

CAP Response:

The inspection team leader is responsible for reviewing the application packet for the laboratory and tailors the composition of each inspection team to provide a "peer review" of the laboratory's services. **If the team leader has members of his/her staff (pathologists, doctoral scientists, and medical technologists) which he/she believes would be appropriate for review of the inspectee's lab, such personnel are used on the team.** If such personnel are not available within the team leader's staff, individuals with the desired expertise are frequently drawn from other laboratories with which he/she is acquainted.

We have not seen any indication that use of team members from a team leader's laboratory results in less objectivity in the inspection than if team members are selected from other facilities. **The detailed questions in the checklists facilitate "yes, no, or not applicable" responses, thereby minimizing the need for subjective decisions.** The Regional Commissioner reviews all inspection packets and the Commission chairman randomly reviews approximately 5 % of all inspection documentation. These procedures help to assure a uniform application of the program.

College of American Pathologists

(4) How often does the CAP get requests from member labs for inspection teams from a different state or town? What is the CAP's position on such requests?

CAP Response:

There is no requirement that a laboratory be a "member" lab (i.e., directed by a CAP member). We will inspect any laboratory that meets our criteria for inspection regardless of whether the director is a CAP member. Moreover, the same laboratory evaluation process is followed regardless of whether or not the inspected lab is a "member" lab.

Usually the CAP Regional Commissioner attempts to assign inspection teams from a geographical area different from the area of the lab to be inspected. This may be a different city or in many cases a different state. This is done as a matter of general policy to minimize potential conflicts of interest or concerns about "cronyism". Also we try to insure that inspectors are not assigned to inspect labs from which teams have come to inspect their laboratories. Whenever a laboratory objects to the team which has been assigned, we attempt to determine the reason for the objection. We will change the team as long as it does not compromise the objectivity of the inspection.

(5) How many CAP-accredited labs perform cytology testing? Are CAP inspectors specifically trained in cytology?

CAP Response:

In the CAP Laboratory Accreditation Program, cytology is considered as a subsection of anatomic pathology; therefore, we do not maintain records of specific accreditation in cytology. Although information regarding cytology operations and personnel is requested in the application packet, this packet is not retained after the inspection has been completed and accreditation has been awarded. From a review of 60 inspection packets currently being processed at the CAP office when your letter was received, the following data was obtained: (1) Of 49 hospital laboratories, 33 (67.3%) indicated that cytology is performed; (2) Of 10 independent laboratories, 9 (90%) indicated that cytology is performed; and (3) One clinic laboratory indicated that cytology is performed. **This random sample suggests that approximately 71.6% of inspected labs are performing cytology.**

All general pathologists are trained in cytology as a part of their residency program. This training includes both the interpretative and technical aspects of cytologic examination. Many pathologists take fellowships of varying length in cytopathology to increase their expertise. Some pathologists are certified by the International Society of Cytology and **the American Board of Pathology will soon begin examining for special competency in cytology.** The procedural techniques and subjective judgement processes used in review of cytology material and anatomic pathology specimens are basically the same. The Anatomic Pathology Checklist section includes a subsection on cytology and the inspector workshops include cytology in this section.

(6) How often does the Regional Commissioner, in reviewing inspection reports, modify the recommendations of the inspection team?

CAP Response:

The primary function of the inspection team is to review what the laboratory is doing and to submit data regarding these activities pursuant to specific questions in the Checklists. Deficiencies are identified and discussed with the inspected laboratory's personnel during the summation conference. Subsequently, the laboratory is provided with a computer print out of deficiencies and a letter from the Regional Commissioner requesting that it respond to each of them. Once the Regional Commissioner receives these responses, he/she reviews them to assure that deficiencies have been corrected and that compliance with the Standards for Accreditation has been achieved. Consequently, **the Regional Commissioner does not "modify" the recommendations of the inspection team, but is responsible for determining if the laboratory has made the necessary changes to qualify for accreditation.**

(7) Does the CAP use on-site proficiency testing as part of its inspection process? If on-site P.T. is no longer used, what was the rationale for stopping this practice?

CAP Response

The CAP has not used on-site proficiency testing as part of its inspection process for many years. As acknowledged by Dr. Axelrod of New York State in his recent testimony before Congressman Wyden's Subcommittee, **little difference in performance is observed between on-site and quarterly mailed proficiency testing.** However, New York State's program continues to use on-site p.t.

By their nature, proficiency testing samples at best represent only an adequate simulation of a patient sample. Through mailed samples, specimens are handled in a manner consistent with specimens received by the lab in its ordinary course . In this manner, potential stability changes are the same for all participants.

With on-site proficiency testing, samples are handled at the discretion of the individual inspector. This may introduce variables from sample to sample and laboratory to laboratory. As a consequence of such possible deviations and since little additional knowledge can be obtained through on-site testing the CAP believes that this practice represents an increase in costs with no associated benefits.

(8) How many labs received at least one Phase II deficiency in their last on-site inspection (in either 1986 or 1987)? What was the average number of Phase II deficiencies received? What was the range in the

number of Phase II deficiencies? Which particular Phase II deficiencies were most often cited?

CAP Response

CAP records and computer programs are not designed to facilitate ready retrieval of information assessing the number of laboratories which received at least one Phase II deficiency in their last inspection or the average number of Phase II deficiencies per laboratory. The extent of programming required to obtain this information could not be completed in the time allowed for preparation of this response. However, **it is rare that a lab will have no Phase II deficiencies.** This is partially due to the constant updating of the Checklists with new questions and requirements. We believe that **most laboratories will have from one to five Phase II deficiencies noted during the inspection.** New laboratories applying for the first time to the CAP Laboratory Accreditation Program tend to have larger numbers of Phase II deficiencies which have been corrected on subsequent inspection cycles. Inspection of a recent laboratory revealed 49 Phase II deficiencies. This laboratory did not achieve accreditation and was encouraged to reapply when it was better prepared.

The most common Phase II deficiencies by Checklist section are listed in Appendix 2. All Phase II deficiencies occurring in 5 % or greater of the inspections using that section are identified in that appendix.

(9) What process does the CAP use to bring a laboratory into compliance once a Phase II deficiency has been identified?

CAP Response:

The Regional Commissioner submits the list of Phase II deficiencies to the laboratory director of the inspected laboratory. **The Commissioner requests that documentation of correction be returned within 30 days.** If delays are excessive or if it becomes evident that correction cannot be made within a reasonable time, **the Regional Commissioner will either encourage the laboratory to withdraw or will recommend to the Commission on Laboratory Accreditation that accreditation be denied or rescinded depending on whether the laboratory is a new applicant or a currently accredited laboratory.** If accreditation is rescinded for a laboratory which is using its CAP accreditation to meet Federal or JCAHO requirements, the appropriate agency is notified for action as it deems necessary.

(10) What is the basis of the CAP's two-year inspection cycle? Has the CAP given any consideration to changing the inspection cycle for laboratories?

CAP Response:

The CAP Laboratory Accreditation Program has used one, two, and three year cycles during its 27 year history. **After much review, the two-year cycle has been accepted by the Commission as the most efficient method of reviewing laboratories and encouraging continued compliance with the Standards.** Each laboratory is required to complete a self-evaluation in the interim year using the same checklists as used in the regular inspection. The results of this review are submitted to the CAP and deficiency lists are prepared. When deficiencies are noted, the laboratories are required to take corrective action. This action must be documented for reference at the next on-site inspection. Regional Commissioners are routinely notified of laboratory deficiencies within their jurisdictions. The Commissioner may request corrective action from the laboratory.

Pursuant to CLIA requirements, the CAP formerly inspected all CAP laboratories using their participation for exemption for CLIA on an annual basis. **In 1981 the CDC conducted a study to see if this cycle could be extended for laboratories which had been in the CAP program for several cycles.** The following overview of this study is extracted from an April 1981 cover letter from Carl Blank, Ph.D., Chief, Examination and Documentation Branch, and Sam Caudhill, Statistician, Program Coordination Activity to Louis LaMotte Jr. Sc.D. Director, Licensure and Proficiency Testing Division:

> "At the request of the College of American Pathologists (CAP) we have undertaken a review of the CAP's experience with laboratories accredited under the one-year and two-year inspection cycles. The purpose of the review was to consider the feasibility of permitting the CAP to inspect those CAP laboratories holding Letters of Exemption from interstate licensure every other year, rather than annually."......
>
> "Numerically the differences in deficiencies observed by CAP between the one and two-year cycle laboratories are so small, that even when statistical significance of the differences can be established, the **practical differences may not be sufficient to justify the requirement for annual inspections."......**

As a result of this study, an agreement was reached by CAP, CDC, and HCFA that, under certain conditions, most CAP laboratories using their accreditation for CLIA Exemption could be inspected on a two-year cycle. In the following circumstances, laboratories would be subject to a one-year cycle until the CLA was satisfied that a two-year cycle was appropriate: **(1) new applicants; (2) those that demonstrated inordinate numbers of Phase II deficiencies, (3) those that encountered problems in proficiency testing, or (4) those that had changes in ownership, location or major management.**

The CAP Commission on Laboratory Accreditation regularly reviews the inspection cycles to see if other cycles would be more appropriate.

The CAP Standards

(1) You indicated in your testimony that the CAP evaluates the workload of cytotechs as part of an inspection. Does the CAP have a standard regarding other bench workers in labs that are accredited by the CAP?

CAP Response:

The CAP does not have specific workload standards for personnel in

cytology or in other laboratory disciplines for which we accredit laboratories. However, the inspection team does attempt to review the qualifications and workload of the personnel to assess whether the number and training of the personnel are sufficient for the work to be performed.

(2) What is the difference between the CAP's new director standard and its previous director standard? Why did the CAP change this standard?

The laboratory director Standard III in effect from 1982 to 1987 reads as follows:

> A hospital pathology service shall be directed by a physician who is an active member of the medical staff and is qualified to assume professional, organizational, educational, and administrative responsibility for the service. The director of an independent laboratory shall be a physician with training and experience in pathology, or a clinical scientist with adequate training and experience in clinical laboratory work, who meets the requirements of a laboratory director under the Clinical Laboratory Improvement Act of 1967. The director shall be responsible for insuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the pathology service.

Standard I--Director and Personnel Requirements from the 1987 edition of the Standards reads as follows:

> The pathology service shall be directed by a physician who is qualified to assume professional, scientific, consultative, organizational, administrative, and educational responsibility for the facilities or services. Whenever possible, the director shall be a pathologist, preferably one certified by the American Board of Pathology. The director shall assume full responsibility for the operation and administration of the laboratory.
>
> **In the exceptional circumstances when a physician is not available, a doctoral level clinical scientist may serve as director.** Such an individual must be qualified by virtue of documented special training, expertise, and experience in the areas of analytical testing offered by the laboratory. In such cases, the services of a qualified consulting pathologist shall be retained. In all facilities where anatomic pathology services are provided, a pathologist shall perform such services.
>
> Special function laboratories shall be directed by either a physician who is qualified to assume professional responsibility for the special function laboratory or a qualified doctoral level clinical scientist with documented special training, expertise, and experience in the appropriate specific clinical discipline.
>
> The location, organization, or ownership of the laboratory shall not alter the requirements of this Standard, its interpretation, or its application.

College of American Pathologists

A copy of both the 1982 and the 1987 versions of the Standards and their interpretations are included in Attachment 3 for your review.

Over the past several years, the distinction between hospital and independent laboratories has become less clear. For a variety of reasons laboratories located away from hospitals now perform services for hospital inpatients that were previously performed only by laboratories in hospitals. Conversely, hospital laboratories are increasingly doing work for non-patients of the hospital and are therefore acting as independent labs for such patients. **The 1987 Standards were designed to eliminate what was rapidly becoming an artificial distinction between the two kinds of labs.** Throughout the history of the LAP, we always have required that a physician, preferably a board certified pathologist, be the director of a hospital laboratory. However we have accredited independent laboratories that are directed by doctoral scientists. **In 1987 due to the difficulties in distinguishing between these categories, we attempted to establish standards which could be used uniformly across all laboratories. The intent of these changes was to insure that there was sufficient medical input for patient care decisions.**

The 1987 Standards were widely criticized because they appeared to deny CAP accreditation to independent labs directed by qualified non-physicians. In fact despite the wording of the Standard we continued to accredit such labs. We are now in the process of reviewing the Standards to make them conform to our actual practice, i.e. not to deny accreditation to a lab run by a qualified non-physician if the lab otherwise meets our criteria for accreditation.

HCFA Activity Relevant to the CAP

What is your opinion of the oversight HCFA exercises over the CAP with respect to the CLIA program? What sort of information does HCFA request from CAP for labs that are inspected by the CAP or participate in the CAP's proficiency testing program? Has oversight of the CAP under CLIA changed, from the CAP's perspective, since HCFA took over this function from the Centers for Disease Control?

CAP Response:

Prior to, and for a short time after, HCFA took over the monitoring responsibility for CAP Laboratories from CDC, the CAP and CDC held annual (and sometimes semi-annual) "equivalency meetings." During these sessions, the CAP reviewed with CDC any significant changes projected for the Laboratory Accreditation Program and new programs or modifications which were being introduced into the Surveys. **At least annually, CDC data from random monitoring or validation inspections of CAP accreditated laboratories were reviewed, and any differences resolved.** The CAP found these meetings beneficial and we have urged that they be continued along with the random sampling validation inspections.

In recent years, usually at the CAP's initiative, periodic meetings have been conducted to review areas of mutual interest and to provide input to CLIA or Medicare changes being considered by CDC and/or HCFA. The CAP maintains a standing CAP/HCFA/CDC working committee. Members of this group have met several times with CDC during the past two years to review various aspects of the Uniform Proficiency Testing Proposal. CAP still provides information on Surveys changes to both agencies and provides updated copies of the Checklists and the Standards as these are modified. At least two detailed "technical reviews" of the CAP programs have been conducted by CDC and HCFA personnel as they considered the CAP applications for "Deemed Status." **To our knowledge no monitoring or validation inspections have been conducted for several years.**

CAP regularly provides data to both state agencies acting on behalf of HCFA and to the CDC on Surveys performance for Medicare and CLIA participants for those who have authorized provision of such data. Inspection data is provided on request to the appropriate agency for laboratories using their CAP participation in lieu of CLIA licensure. For those participants using CAP participation to meet JCAHO requirements, we have an agreement with JCAHO to provide inspection data to it on request.

The CAP believes that frequent dialogue between CAP and the federal agencies responsible for monitoring laboratory improvement programs is productive, and we would encourage semi-annual meetings. Through our Commission on Scientific Resources, the Commission on Laboratory Accreditation, and the 16 resource committees, we have the most extensive body of expertise in the world relating to laboratory improvement efforts. We regularly have offered our consultation and continue to encourage the federal agencies to employ our expertise as we mutually work toward assurance of quality laboratory services for all patients.

Thank you for the opportunity to present testimony and for your interest in CAP Laboratory Improvement Programs. If we can be of further assistance, please contact Mr. Al Ercolano at our Washington Office.

Sincerely,

Loyd R Wagner

Loyd R. Wagner, MD, Vice President
College of American Pathologists

Cohen488

Attachment 1

AGENDA
INSPECTOR'S SEMINAR
April 29, 1988
Cleveland, Ohio

8:15-8:30	Introductory remarks	Dr. Hoeltge
8:30-9:00	The Laboratory Accreditation Program in 1988	Dr. Batjer
9:00-9:30	Quality Assurance and Standard III	Dr. Baker
9:30-9:50	Special QA Issues in Anatomic Pathology	Dr. Rickert
9:50-10:10	Documentation of QA in Clinical Pathology	Dr. Vennart
10:10-10:30	Break	
10:30-12:00	Group Discussions	
	I. Inspecting a laboratory's QA program	Drs. Baker, Bachner & Rickert
	II. Uniform interpretation of Standard I from an Inspector's point of view	Drs. Peters & Batjer
	III. Very small laboratories; special function laboratories; remote laboratories	Drs. Dynek, Merrick & Vennart
	IV. Proprietary hospital laboratories; independent, commercial laboratories	Drs. Sarewitz & Barr
	V. New Inspector's orientation	Dr. Simard, Sulak & Region 8 State Commissioners

(Governors and Other Commissioners may select any discussion group.)

12:00-1:30 Lunch -- Speaker: **William B. Zeiler, MD, CAP President**

Reports from the Group Discussions

1:30-1:45	Group I - Dr. Baker	
1:45-2:00	Group II - Dr. Peters	
2:00-2:15	Group III - Dr. Dynek	
2:15-2:30	Group IV - Dr. Sarewitz	
2:30-2:45	Microbiological Safety Issuses and Accreditation	Dr. Merrick
2:45-3:00	Toxic Substances in the Laboratory	Dr. Hoeltge
3:00-3:15	Break	
3:15-3:30	Participation in the Surveys Program	Dr. Barr
3:30-4:00	Forensic Urine Drug Testing Program	Dr. Butler
4:00-4:15	Central Office Report	Ms. Hopewell
4:15-4:30	Questions/Answers and Wrap-up	Dr. Hoeltge

Seattle, Washington
August 14, 1987

QUALITY ASSURANCE IN THE CLINICAL LABORATORY
AN ACCREDITATION VIEWPOINT

Registration 7:45-8:15

Introductory Remarks 8:15-8:30
(Dr. John Batjer)

Quality Assurance-JCAH Perspective 8:30-9:00
(Dr. Glen Baker)

Director of Laboratories
and Quality Assurance 9:00-9:30
(Dr. John Duckworth)

Quality Assurance in the General
Lab-An Overview 9:30-10:15
(Dr. Paul Bachner)

Coffee Break
10:15-10:30

Quality Assurance-Specific Examples

Anatomic Pathology 10:30-11:00
(Dr. Robert Rickert)

Roundtable Discussion (Open forum for
discussion of Quality Assurance,
Laboratory Accreditation Program, other) ..11:00-to lunch

Lunch

Report from Board of Governors ......William B. Hamlin, M.D.

Quality Assurance-Specific Examples
continued 1:00-4:00

Immunohemtology 1:00-1:30
(Dr. Gerald Hoeltge)

Chemistry/Toxicology 1:30-2:00
(Dr. George Vennart)

Hematology 2:00-2:30
(Dr. John Batjer)

Break
2:30-2:45

Microbiology/Bacteriology 2:45-3:15
(Dr. Thomas Merrick)

Quality Assurance-CAP Perspective 3:15-3:45
(Dr. Glen Baker)

Question and Answer 3:45-4:00

Laboratory Accreditation Program Phase II Deficiency Report

Attachment 2

Section 01

Question #	# of Deficiencies Reported	% of Total Respondents
01.1380	214	8.56
01.0525	204	8.16
01.0820	198	7.92
01.0170	188	7.52
01.0550	181	7.24
01.0520	157	6.28
01.0540	152	6.08
01.0530	131	5.24

Section 02

Question #	# of Deficiencies Reported	% of Total Respondents
02.1050	196	9.02
02.0090	169	7.78
02.0080	162	7.45
02.0482	157	7.22
02.0420	155	7.13
02.1450	137	6.30
02.0453	133	6.12
02.1008	118	5.43
02.0615	113	5.20
02.0100	110	5.06

Section 03

Question #	# of Deficiencies Reported	% of Total Respondents
03.0090	245	10.91
03.0080	216	9.62
03.0460	213	9.48
03.0390	192	8.55
03.0350	185	8.24
03.0070	181	8.06
03.0530	143	6.36
03.0100	131	5.83
03.0740	117	5.21

Laboratory Accreditation Program Phase II Deficiency Report

Section 03A

Question #	# of Deficiencies Reported	% of Total Respondents
03A.0360	154	7.19
03A.0080	151	7.05
03A.0090	128	5.98
03A.0420	107	5.00

Section 03B

Question #	# of Deficiencies Reported	% of Total Respondents
03B.0390	57	7.56
03B.0090	54	7.17
03B.0080	52	6.90
03B.0430	50	6.64
03B.0100	41	5.44

Section 04

Question #	# of Deficiencies Reported	% of Total Respondents
04.0390	160	7.61
04.0080	140	6.66
04.0090	124	5.90

Section 05

Question #	# of Deficiencies Reported	% of Total Respondents
05.0384	196	10.27
05.0495	107	5.61
05.0630	104	5.45
05.0395	100	5.24

Laboratory Accreditation Program Phase II Deficiency Report

Section 06

Question #	# of Deficiencies Reported	% of Total Respondents
06.0080	165	7.83
06.0370	119	5.64

Section 07

Question #	# of Deficiencies Reported	% of Total Respondents
07.0060	90	10.63
07.0050	81	9.57
07.0380	78	9.21
07.0070	72	8.51
07.0040	65	7.68
07.0480	60	7.09
07.0020	59	6.97
07.0320	57	6.73
07.0785	50	5.91
07.0440	45	5.31
07.0310	44	5.20
07.0490	43	5.08

Section 07A

Question #	# of Deficiencies Reported	% of Total Respondents
07A.0020	13	11.60
07A.0370	12	10.71
07A.0050	11	9.82
07A.0060	10	8.92
07A.0280	9	8.03
07A.0390	9	8.03

Section 08

Question #	# of Deficiencies Reported	% of Total Respondents
08.0730	172	9.30
08.0820	172	9.30
08.1030	104	5.62
08.1090	98	5.30
08.1990	95	5.14

Laboratory Accreditation Program Phase II Deficiency Report

Section 09

Question #	# of Deficiencies Reported	% of Total Respondents

****

NO QUESTIONS RECEIVED A DEFICIENCY RESPONSE IN EXCESS OF 5%

Section 10

Question #	# of Deficiencies Reported	% of Total Respondents
10.0720	7	6.93
10.0530	6	5.94
10.0590	6	5.94

Section 25

Question #	# of Deficiencies Reported	% of Total Respondents
25.3960	65	10.20
25.3930	64	10.04
25.3950	63	9.89
25.0330	54	8.47
25.0320	53	8.32
25.0310	50	7.84
25.3940	45	7.06
25.3920	42	6.59
25.4050	41	6.43
25.0490	40	6.27
25.4080	40	6.27
25.4180	38	5.96
25.4430	36	5.65
25.0675	34	5.33
25.4110	34	5.33
25.1200	33	5.18

STANDARDS
FOR
LABORATORY
ACCREDITATION

1982 EDITION

COLLEGE OF AMERICAN PATHOLOGISTS
7400 NORTH SKOKIE BLVD /SKOKIE ILLINOIS 60077
(312) 677-3500

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PREFACE

The College of American Pathologists established the Laboratory Accreditation Program in 1961 to conduct a program of voluntary peer review and education designed to improve laboratories and the quality of their services. Since then, the Commission on Laboratory Accreditation has conducted a voluntary program designed to fulfill those objectives.

The Standards for Laboratory Accreditation were developed by the Commission on Laboratory Accreditation to ensure quality pathology services. The scope of the Accreditation Program encompasses a diverse range of services and facilities, from the complex, sophisticated laboratory procedures performed in large tertiary care hospitals to less complex procedures encountered in smaller laboratories.

A responsive and detailed checklist and commentary has evolved from the requirements of the Standards of the Laboratory Accreditation Program. The checklist format permits a comprehensive evaluation of a laboratory's compliance with the Standards.

STANDARD I

THE PRACTICE OF PATHOLOGY IS ESSENTIAL TO PATIENT CARE. THE PATHOLOGIST AND THE LABORATORY STAFF SHALL PROVIDE APPROPRIATE SERVICES, INCLUDING, BUT NOT LIMITED TO, THE EXAMINATION OF PATIENT RELATED SPECIMENS, CLINICAL INTERPRETATION AND CONSULTATION, SCIENTIFIC INVESTIGATION, AND EDUCATION IN ORDER TO BE EFFECTIVE IN THE PREVENTION, RECOGNITION, DIAGNOSIS, TREATMENT, AND PROGNOSIS OF DISEASE.

INTERPRETATION:

The laboratory's staff within a hospital or other location is concerned with the examination and analysis of specimens from patients, the examination of patients in appropriate consultation cases, and the participation in the prevention, monitoring, diagnosis, and treatment of disease. The complexity and sophistication of these procedures will vary in different situations.

The pathologist is ultimately responsible for all operational aspects of the laboratory, and for the evaluation and interpretation of results of various laboratory examinations. The pathologist's activities affect each patient directly and indirectly and are medical services requiring a comprehensive knowledge of laboratory procedures and clinical medicine.

Each pathology service shall provide educational activities for the medical staff, pathology department staff, trainees in pathology and technology, and other appropriate personnel.

STANDARD II

THE LABORATORIES SHALL HAVE SUFFICIENT SPACE, EQUIPMENT, FACILITIES, AND SUPPLIES FOR THE PERFORMANCE OF THE REQUIRED VOLUME OF WORK WITH ACCURACY, PRECISION, EFFICIENCY, AND SAFETY; IN ADDITION, THE LABORATORIES SHALL HAVE METHODS FOR COMMUNICATION TO ENSURE PROMPT, RELIABLE REPORTING AND APPROPRIATE RECORD STORAGE AND RETRIEVAL.

INTERPRETATION:

The scope of the responsibilities and activities of the laboratory must be delineated. Once this determination has been made, sufficient space, equipment, and qualified personnel must be provided.

The environment within the laboratory shall be conducive to effective performance of personnel and equipment. Work assignments shall be consistent with the qualifications of the technical personnel. There shall be sufficient, conveniently located bench and storage space for the proper handling of specimens and housing of equipment and reagents. Special areas for tests requiring a controlled environment shall be provided. Work areas shall be arranged to minimize transportation and communication problems, and shall be adequately lighted to facilitate performance of analytical procedures.

Facilities for communication (interdepartmental and intradepartmental) shall be appropriate for the size and complexity of the organization in order to provide the most efficient operation.

Facilities, equipment, and instruments shall be appropriate for the services performed and must be maintained in a demonstrably functional condition.

The laboratory must be a safe working place for the personnel and for the patients it serves. The laboratory must be in compliance with the relevant safety codes of the appropriate jurisdictional authority and of the federal government. The safe handling of patient samples and of reagents shall be an integral part of the laboratory safety program. Proper disposal of hazardous wastes shall be provided.

A hospital laboratory must have the capability or provision for the prompt performance, at any time, of those procedures necessary to aid emergency diagnosis and guide emergency treatment as specified by the laboratory director with the concurrence and consultation of the medical staff.

The performance of tests in off-site facilities is acceptable only if test results are readily available and are of comparable quality to those provided in on-site facilities, and if the time interval from ordering to reporting is commensurate with good patient care.

If tests are to be referred to off-site and/or remote facilities, the laboratory director or consulting pathologist shall select the referral laboratory (laboratories) on the basis of objective evidence of acceptable quality. Except where special circumstances dictate otherwise, tests should be referred only to laboratories that have been accredited by CAP, licensed under the Clinical Laboratories Improvement Act of 1967 (CLIA), or that otherwise demonstrate ability to perform the referred tests with the required accuracy and efficiency.

STANDARD III

A HOSPITAL PATHOLOGY SERVICE SHALL BE DIRECTED BY A PHYSICIAN WHO IS AN ACTIVE MEMBER OF THE MEDICAL STAFF AND IS QUALIFIED TO ASSUME PROFESSIONAL, ORGANIZATIONAL, EDUCATIONAL, AND ADMINISTRATIVE RESPONSIBILITY FOR THE SERVICE. THE DIRECTOR OF AN INDEPENDENT LABORATORY SHALL BE A PHYSICIAN WITH TRAINING AND EXPERIENCE IN PATHOLOGY, OR A CLINICAL SCIENTIST WITH ADEQUATE TRAINING AND EXPERIENCE IN CLINICAL LABORATORY WORK, WHO MEETS THE REQUIREMENTS OF A LABORATORY DIRECTOR UNDER THE CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967. THE DIRECTOR SHALL BE RESPONSIBLE FOR ENSURING THAT THERE ARE SUFFICIENT PERSONNEL WITH ADEQUATE TRAINING AND EXPERIENCE TO SUPERVISE AND CONDUCT THE WORK OF THE PATHOLOGY SERVICE.

INTERPRETATION:

The director of a hospital department of pathology shall be an active member of the medical staff, preferably certified by the American Board of Pathology, and shall assume full responsibility for the operation and administration of the department.

The pathologist and/or the pathology staff shall be available to consult with fellow physicians relating to the medical appropriateness of laboratory data in the diagnosis, management, and prognosis of patients' medical problems. The pathologist shall serve as the medical liaison between the medical staff and its patients and the hospital administration in effecting the most appropriate use of laboratory resources.

When a pathologist is not available, a qualified doctor of medicine who is a member of the medical staff of the hospital shall be responsible for the hospital laboratories. In this event, the services of a consulting pathologist shall be retained, if possible. The consulting pathologist shall also be a member of the medical staff and shall be eligible to serve on medical staff committees. A close working relationship between the staff physician in charge of laboratories and the consulting pathologist must be established. In all instances, the physician in charge of the laboratory and the consulting pathologist must establish an effective working relationship with the hospital administration, the medical staff, and other hospital departments and services. Each shall play an active role in the educational programs of the laboratories and of the hospital.

There shall be a sufficient number of qualified professional and technical staff in all areas in order to perform promptly and proficiently the tests and examinations required of the pathology service. All tests performed in the medical laboratories must be carried out by qualified personnel using validated methods of acceptable high quality. The competency of the personnel and the selection of methods shall be the responsibility of the laboratory director.

STANDARD IV

EACH LABORATORY, WHETHER A HOSPITAL OR INDEPENDENT LABORATORY, SHALL HAVE A QUALITY CONTROL SYSTEM DESIGNED TO ASSURE THE RELIABILITY AND MEDICAL USEFULNESS OF LABORATORY DATA.

INTERPRETATION:

A laboratory quality control system shall contain the following components: 1) The selection of test methods appropriate to the medical requirements of the patients served, 2) An internal quality control system which monitors precision of laboratory performance on a daily basis. 3) An interlaboratory comparison system (proficiency testing) designed to compare laboratory performance with other laboratories; 4) An instrument maintenance program which monitors and assures the proper calibration and functioning of equipment, 5) An educational program for the entire laboratory staff designed to maintain or improve the quality of personnel performance, 6) An external audit or accreditation process; 7) Appropriate documentation for the foregoing.

Procedure manuals should follow a standard format and indicate test sources, dates of adoption, and evidence of ongoing review.

Methods and instruments shall be validated when introduced and when reintroduced following correction of an "out of control" situation. Every component of every instrument ages and deteriorates with use; therefore, a complete quality control program must include regular preventive maintenance and appropriate function checks.

Written instructions shall be available that provide, in detail, the methods for procuring, transporting, and processing appropriate specimens. There shall be a written description of the system for the timely reporting of patient data to the physician and of the safeguards taken to ensure the correctness of that data.

Programs for surveillance and control of incoming materials will ensure that all reagents, specimens, and materials utilized at the analytical bench have the properties necessary for reliable performance.

Participation in proficiency testing surveys compares the laboratory performance with the consensus of referee and peer laboratories, and verifies the validity of calibration and test procedures. The laboratory shall participate regularly in College Surveys programs covering those types of testing the laboratory regularly provides.

If any Survey results are unsatisfactory according to the criteria of the testing agency, the cause of the unsatisfactory result must be investigated and corrected when possible. The pertinent findings of the investigation and the corrective measures instituted must be recorded, dated, and signed by the responsible technologist or supervisor and the pathologist or laboratory scientist.

Quality control applies equally to anatomic pathology. A written surveillance program of the quality of surgical pathology and cytopathology diagnoses may include, but is not limited to, the use of intra- and extradepartmental consultation, circulation of diagnostic material (random or by case type), archival case review, correlation of histological and cytological material, and the periodic review of completed diagnostic reports. The program will depend upon variables such as the size of the departmental staff and the volume and type of diagnostic material processed.

The laboratory shall submit to periodic inspection and evaluation as determined by the Commission on Laboratory Accreditation of the College of American Pathologists.

Joint Commission

April 26, 1988

Chairman
Subcommittee on Oversight
  of Government Management
Committee on Governmental Affairs
United States Senate
Washington, DC 20510-6250

Dear Sir:

We are writing in response to your letter of April 14, 1988 which seeks our views on a number of issues surrounding the subject of assuring quality in clinical laboratory testing. We understand that the questions you raise and our responses will be included in the record of your March 24 hearings on this subject. Our item-by-item reponses are attached.

We trust that the enclosed information is fully responsive to your questions. If you feel we have not adequately addressed these issues or if you have additional questions or concerns, we would be pleased to provide a further response.

Sincerely,

Dennis S. O'Leary, M.D.
President

DSO/ad

Enclosure

cc: The Honorable Carl Levin
    United States Senate

    The Honorable William S. Cohen
    United States Senate

Joint Commission

Joint Commission Response
to Questions Raised by
the Subcommittee on Oversight of Government Management
Committee on Governmental Affairs

The Relationship Between HCFA and the Joint Commission

1.a. If asked, would you provide HCFA with the results of all your inspections, or at least those in which contingencies were awarded?

The Joint Commission presently provides HCFA with the accreditation decision respecting all hospitals. We also provide HCFA with a copy of the accreditation report for every hospital subjected to a Medicare validation or complaint investigation survey upon receipt of a request from HCFA to do so. With respect to these latter cases, we have copies of authorizations from accredited hospitals to release their reports to HCFA.

In accordance with current policies, we would not provide HCFA with data concerning the existence or nature of accreditation contingencies or copies of accreditation reports beyond the limits described above unless we had an authorization from a hospital to do so. **If the federal government determined a need to alter this fundamental characteristic of the existing Medicare deemed status relationship, the Joint Commission would evaluate the implications of such a change and advise the government of its decision.**

1.b. Would a request from HCFA be sufficient, or is it the Joint Commission's view that legislation requiring that such information be provided as a condition of deeming would be necessary?

Hospitals apply to participate in the Joint Commission accreditation process with the understanding that the Joint Commission will hold the results and recommendations of their survey as confidential matters between the Commission and the hospitals, absent written authorization for further disclosure. The current wording of Section 1865 of the Social Security Act tends to reinforce this confidential relationship. **We therefore believe that legislation would probably be needed to effect this change.**

2.a. Has HCFA asked the Joint Commission, informally or formally, for such information in the past?

HCFA has never formally or informally sought a copy of a hospital accreditation report from the Joint Commission except for those reports specified at Section 1865(a)(2) of the Social Security Act. **HCFA staff, on one occasion, directed an inquiry to Joint Commission staff concerning the possibility of obtaining copies of the College of American Pathologist (CAP) reports used by the Joint Commission in evaluating hospital performance against accreditation standards with respect to those facilities subjected to Medicare validation and complaint surveys. Without replying positively or negatively to this inquiry, Joint Commission staff suggested that HCFA contact CAP relative to this matter. This issue was subsequently not further pursued with the Joint Commission by HCFA.**

2.b. What was the Joint Commission's response?

Please refer to the response to question 2.a. above.

3.a. According to Joint Commission records, how many hospitals were included in HCFA's validation surveys in the years 1984-1987?

According to Joint Commission records the following numbers of accreditation reports were provided to HCFA for the fiscal years in question:

	FY 84	FY 85	FY 86	FY 87
No. of Reports	73	108	93	61*

* No. of reports requested by HCFA to date; the Joint Commission ordinarily receives multiple requests each year covering the prior FY.

3.b. Does this number include HCFA surveys that were based on a complaint against a hospital?

Except for 1987, the number presented above includes both validation and complaint investigation surveys. The 61 reflected to date for 1987 are sample validation surveys only. It should be noted that **HCFA does not make a practice of seeking copies of accreditation reports respecting hospitals subjected to complaint investigations unless the complaint is verified.** HCFA performed over 850 complaint investigations during the period October 1, 1983 through September 30, 1986 where no request was made to the Joint Commission for copies of an accreditation report.

Inspections

1.a. You indicated in your testimony that the Joint Commission conducts unannounced inspections for cause. In 1986 and 1987, how many unannounced inspections were performed.

The Joint Commission conducted 20 unannounced/unscheduled hospital surveys for cause in 1986 and 1987.

1.b. What were the results?

A recapitulation of the results of these surveys follows:

Result	Frequency
- Hospital notified of pending nonaccreditation	4
- Focused visit contingency imposed on continuing accreditation	8
- Survey findings added to results of most recent full survey findings	1
- Contingency report imposed as a condition of continuing accreditation	3
- Joint Commission Laboratory Technologist added to survey team for hospital with CAP accredited laboratory	1
- Failed to verify validity of complaint/or complaint verified but hospital had completed actions to correct problem and prevent recurrence	3
Total	20

1.c. Were these results different from what was found in the normally scheduled announced inspections of these facilities?

Generally, it may be said that the Joint Commission discovered problems which either were not apparent in its previous survey or which occurred subsequently.

1.d. How many of these unannounced inspections were performed for a cause relating to the hospital laboratory?

Two of these unannounced surveys were performed for a cause relating to the hospital laboratory--one stemming from a reported blood transfusion problem and one relating to allegations of inadequate clinical laboratory supervision. In both instances, the on-site visit by Joint Commission staff verified the alleged problems but also revealed that the hospitals, having been alerted to the problems, had taken appropriate action to correct them and

to prevent their recurrence. No adverse accreditation actions were implemented in either case; however, as pointed out above, one instance led to a Joint Commission decision to require participation of a Joint Commission laboratory technologist in the facility's next survey, its CAP accreditation notwithstanding.

Evaluating Lab Quality

1.a. Please describe your project to build outcome evaluation into the quality assurance process mentioned briefly in your testimony. What exactly is involved?

Historically the Joint Commission accreditation process has involved an assessment of an institution's compliance with accepted standards of structure and process and has been designed to answer the following basic questions: "Can this organization provide quality health care?"; "Does this organization provide a safe environment in which to render health care?"; and "Does this organization have effective mechanisms for identifying problems, resolving them and forestalling their recurrence, and are these mechanisms being employed?". Drawing upon the rapidly evolving and substantial clinical and organizational research literature and recognizing the importance of more direct evaluation of performance, the Joint Commission has embarked on a major set of initiatives to fundamentally change the nature of its accreditation process. Our objective is that the accreditation process answer the question, "Does this organization provide quality health care?".

The integrals of the aforementioned Joint Commission initiative include:

- Creation of an in-house research capacity (completed in 1987)
- Research and development focused on clinical outcome indicators (initiated in 1987)
- Convening of panels of experts in various clinical disciplines for the purpose of identifying appropriate clinical outcome and process indicators (initiated in 1987 in the areas of Anesthesiology, Obstetrics, Hospital-wide indicators, e.g. nosocomial infection rate). Organization and management indicators are also being developed. In 1988, expert panels are being convened to identify in-hospital and ambulatory care indicators in the areas of cardiovascular care, oncology care, general surgery, trauma care, long term care, and mental health.

- Testing of indicators in a diverse sample of hospitals (initiated in 1987)

- Development of clinical indicator risk adjustment factors in recognition of fact that clinical outcomes are affected both by patient comorbid conditions and socioeconomic status (ongoing)

- Development of ongoing routine reporting links between facilities involved in the accreditation process and the Joint Commission wherein clinical and organization indicator data will be reported to the Joint Commission, and the Joint Commission will provide data to facilities concerning comparative performance with like facilities. The evaluation of this system, which is designed to sharpen problem identification, is currently underway.

- Effecting incremental changes in the accreditation process to reflect the application of clinical indicators (to be initiated in 1988)

- Securing foundation financial support for the Joint Commission initiatives (successfully initiated in 1987 and ongoing)

- Full implementation of these initiatives by 1991

- Continuing support for a major research endeavor with respect to evolving concepts of quality of care evaluation (ongoing).

1.b. Is this an approach that could work for evaluating independent laboratories or physician office labs?

We believe this is an approach that can be applied to evaluation of hospital laboratories; it is not clear that the method would be workable with respect to independent physician office labs. We believe it will be feasible for a group of recognized experts in the clinical laboratory testing area to reach a consensus as to indicators which would serve to alert the laboratory itself and its customers (hospital staff for example) of the possible existence of a laboratory problem. In a hospital setting, these problems, in our view, would be documented in clinical records. We are persuaded that in a hospital setting the first evidence of clinical laboratory quality assurance problems surfaces not as a derivative of proficiency testing program results but rather from situations where laboratory results are inconsistent with the clinical evaluations of attending physicians. Such physicians are not reticent about documenting such problems nor are there conflict of interest considerations.

1.c. How would it assist in evaluating the quality of lab work done at night or on the "graveyard" shift?

In a hospital setting, the time during which laboratory work is performed is not a basic issue as long as the results are provided in a timely fashion. There is concern whenever work of inadequate quality is evident. As noted above, this ordinarily first surfaces when laboratory results are inconsistent with other clinical findings.

1.d. Could it work nationally?

We believe the methods described could work nationally with respect to hospitals and other health care organizations.

1.e. Do you believe that the CDC or some other federal agency has the necessary expertise to implement such a system?

We believe the CDC or some other federal agency could convene clinical laboratory experts and could develop a consensus concerning a set of indicators which could serve to alert various publics to the possibility of the existence of significant clinical laboratory quality assurance problems. It is not clear how the public would view such an endeavor by government. For example, some might perceive any governmental endeavor in any clinical area as being more political that scientific. Further, it might be argued by some publics that government implementation of such a program could take on the police power characteristics of a regulatory program, thus creating disincentives for problem documentation and reporting.

Northern Virginia Doctors' Hospital

1.a. How recently had this hospital been inspected and accredited by the Joint Commission prior to October 1978 and October 1979?

Northern Virginia Doctors' Hospital was surveyed and accredited for two years effective March 1978.

1.b. What were the results of the inspections at that time?

The hospital was accredited for two years.

1.c. Were any problems or deficiencies found in the hospital lab?

We have not retained the records of our surveys prior to 1982. It is likely that some laboratory problems were cited since this is almost always the case. At the same time, it is certain that we found the clinical laboratory in this hospital in substantial compliance with our standards in view of the fact that the hospital obtained a two-year accreditation.

1.d. If so, what was the nature of those problems, and were they corrected?

As noted in our response to the previous questions, we do not now know the nature of any problems discovered; however, it is certain that any problems that may have been noted were corrected at the time of the next survey in February 1980, since the hospital was again accredited at that time.

2.a. What are the Joint Commission's requirements for lab personnel who review Pap smears?

The following Joint Commission standards relate to personnel qualifications in cytology.

General Personnel Requirements:

PA.1.3 **There are a sufficient number of qualified laboratory technologists and supportive technical staff to perform, promptly and proficiently, the tests required of the pathology and medical laboratory services.***

PA.1.3.1 A qualified medical technologist

PA.1.3.1.1 is a graduate of a medical technology program approved by a nationally recognized body or has documented equivalent education, training, and/or experience;

PA.1.3.1.2 meets any current legal requirements of licensure or registration; and

PA.1.3.1.3 is currently competent in the field.

PA.1.3.2 The director of the pathology ad medical laboratory services assures that procedures and tests that are outside the scope of education, training, and experience of the individuals employed to perform technical procedures in the laboratory are not performed in the pathology and medical laboratory services.*

PA.1.3.3 At least one qualified medical technologist is on duty or available at all times.*

PA.1.3.4 Work assignments in the pathology and medical laboratory services are consistent with the quaLifications of the employee.*

Cytology Requirements:

PA.6.1.3.1 A cytopathology service that is adequate to meet the needs of the hospital is available.

PA.6.1.3.2 the quality of the cytopathology service is assured through direct supervision by a pathologist or other physician qualified in cytology.*

PA.6.1.3.2.1 This individual reviews all slides of extragenital tract origin and a random sample of negative reproductive tract slides.*

PA.6.1.3.3 All abnormal smears are evaluated by a pathologist or other designated qualified physician.*

PA.6.1.3.4 Abnormal smears are kept on file for as long as needed for patient care purposes and in accordance with applicable law and regulation.

PA.6.1.3.5 Normal smears are kept on file in accordance with applicable law and regulation.

PA.6.1.3.6 Reports of abnormal or suspicious smears are authenticated by a physician who is qualified in pathology or cytology.

* Key standard

2.b. Would Dr. Tong have met those requirements?

As the standards quoted above clearly indicate, the responsibility for assessing the qualifications of the individual providing cytopathology service lies with the hospital and is exercised through the physician director of the clinical laboratory. Our surveyor would have had no disagreement as to the assignment of responsibility for evaluation of Pap smears to a physician board certified in anatomical pathology, as in the instant case, as long as his competence in this procedure had been determined.

2.c. Does the Joint Commission rely on hospitals to determine whether hospital lab personnel are competent in a particular specialty, or do Joint Commission inspectors determine that?

Please refer to our responses to questions 2.a. and 2.b above. Evidence of quality assurance problems in a hospital clinical laboratory in a particular area commonly lead to a surveyor recommendation for reexamination of the relevant personnel credentialing process.

2.d. What level of supervision does the Joint Commission requir of lab personnel who review Pap smears?

Direct supervision of cytology personnel by a pathologist or physician qualified in cytology in contemplated by Joint Commission standards.

3. It is our understanding that neither of Mrs. Johnson's Pap smears--which were classified as "Class II"--were reviewed by Dr. Tong's supervisor or lab director. Does the Joint Commission require tat Pap smears classified as "Class II" be double-checked by a supervisor?

Joint Commission standards contemplate that all abnormal smears be evaluated by a pathologist or other designated qualified physician (see PA.6.1.3.3).

4.a. When and how was the Joint Commission informed of the errors made by the North Virginia Doctors' Hospital lab in reviewing Mrs. Johnson's Pap smears?

The Joint Commission was informed of the alleged errors made by the North Virginia Doctors' Hospital during the course of hearings before the Subcommittee on Oversight of Government Management on the subject of the federal government's role in ensuring the quality of medical laboratory testing on March 24, 1988.

4.b. Is the Joint Commission aware of any changes implemented by the hospital which would reduce the possibility of errors in Pap smear reviews?

The Joint Commission has no records regarding alleged errors that may have been committed in North Virginia Doctors' Hospital. Survey report records concerning this hospital's clinical laboratory in 1984 and 1987 indicate substantial compliance with Joint Commission standards.

4.c. Have there been any changes in Joint Commission requirements or inspection practices since 1979 which would reduce the possibility of errors in Pap smear reviews?

There have been no substantial changes in Joint Commission standards respecting cytology services since 1979. It may be significant to note that in 1979 the Joint Commission added a laboratory technologist to its survey team. Hence, the clinical laboratory area of a hospital has been subjected to a more lengthy and thorough survey subsequent to 1978 than was previously the case.

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SUPPLEMENTAL STATEMENT
OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION
TO
THE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT

This supplemental statement of the American Clinical Laboratory Association ("ACLA") is filed in response to an April 20, 1988, letter from Senators Carl Levin and William S. Cohen seeking additional information from ACLA. For ease of review, this statement will repeat the Senators' questions and then state ACLA's response. This statement is in addition to our written and oral testimony offered to the Subcommittee on March 24, 1988.

Question

> 1. In testimony, Dr. Kaufman mentioned a blind proficiency testing program which SmithKline Bio-Science Laboratories uses as part of its internal quality assurance system. Please describe how this program works? Is this the model for the recommendation for a federal requirement that all labs have their own internal proficiency testing in addition to external proficiency testing?

Response

Smith-Kline Bio-Science Laboratories has explained its blind proficiency testing program as follows:

> Blind testing programs at SKBL have been established to ensure that all laboratory systems are producing data that are accurate, precise, timely, and presented in a format that is professional and informative. Specimens are obtained from patients, normal subjects, outside vendors, or quality control sera with assigned analytical ranges. Both national and local blind proficiency testing is performed on a regular basis. The local quality assurance specialists submit their specimens to the laboratory by the use of blind accounts.

These blind accounts are set up to be indistinguishable from other client accounts and are changed periodically to prevent detection by laboratory personnel.

The objectives of this blind testing program are to evaluate the following:

a. The distribution and entry system, ensuring that the specimen is treated with proper regard for submission requirements and labeling.

b. The accuracy of results by submission of specimens of known concentration.

c. The reproducibility of results (precision) through multiple submissions.

d. The turnaround time from collection to reporting through a review of the final report.

e. The quality of data processing systems. The format of the final written report must be easily readable, contain the correct and appropriate patient and testing information.

f. The accuracy of the billing process, including pricing changes.

National Blind Programs

Testing challenged by the national blind programs includes toxicology (therapeutic drug monitoring and substance of abuse), endocrinology and automated chemistry (including total cholesterol and HDL cholesterol). Cytology and immunology blind programs will be implemented before the end of the year.

The national quality assurance manager sends specimens of known value to each major SKBL laboratory monthly. The local quality assurance specialist returns results to the national quality assurance manager who compiles the data and provides a report back to the laboratories summarizing and comparing site performance. Deficiencies, if present, are cited and corrective actions are required.

Local Programs

The local quality assurance specialist routinely submits specimens utilizing the blind accounts described previously. Testing selected for local blind challenges include:

a. Tests which have had client complaints.

b. New or changed assays.

c. Tests for which there are no external proficiency testing programs.

d. Tests for which there have been external proficiency testing exceptions.

e. At the request of the technical staff.

The results are evaluated by the QA specialist and the national quality assurance manager, and any problems detected are reported to the site management and an "Action Needed Form" is generated. This documentation requires a timely response indicating that the problem identified has been evaluated and corrected.

Many ACLA members utilize programs similar to the one described above. The use of internal, blind proficiency testing programs is desirable; all federally licensed laboratories should engage in similar types of activities. SKBL's program is one approach; there are, of course, others as well, and ACLA would be pleased to work with the Subcommittee to develop language that would establish a requirement that would be broad enough to recognize a variety of approaches but would be specific enough to assure that the intended goals are achieved.

It should also be noted that, in the view of many, an important indicator of laboratory performance is the daily quality control record of each run of a test procedure. The examination of this record by technologists, supervisers, management, and inspectors provides an effective and efficient ongoing verification of the quality of laboratory performance.

Blind internal proficiency testing, as discussed above, is another monitor, and it has the virtue of being an immediate indicator of problems. However, some laboratories question whether such a program could be operated effectively by a small laboratory, especially if the owner/director were one of the primary analysts.

Question

2. Given that the ACLA represents labs that are both accredited by CAP and certified to participate in Medicare, have you formed any opinions about the differences between the CAP and HCFA inspection processes? Is either more stringent, more thorough, more helpful to the lab?

Response

As a general rule, ACLA members feel that the CAP inspections are more thorough than the HCFA inspections. One laboratory responded to this question as follows:

> CAP inspections tend to be conducted by knowledgeable individuals, physicians and pathologists, who are able to inspect for compliance with regulations but appreciate the variety of approaches that may be taken to meet the objective of any given requirement ... i.e., due to their competence, they can have increased flexibility ... HCFA inspection tends to be much less flexible....
>
> CAP inspection more educational for above-reason.... HCFA inspection may not impart much increased knowledge of what is necessary to do good work.
>
> CAP is constantly updating and deleting their requirements ... HCFA regs tend to lag far behind technology....
>
> CAP inspection seems to more effectively integrate the previous periods' proficiency testing results .... Inspectors receive a copy of how the lab has done that permits them to address areas of deficiency .... I haven't seen this done as effectively by HCFA/state inspection.
>
> The thoroughness of CAP and HCFA varies with the inspectors assigned.
>
> Conclusion: CAP inspection generally more thorough with carefully designed and identified requirements that reflect current technology, inspectors generally more competent and able to educate.

Another ACLA member described the differences between the two inspections as follows:

> Generally the CAP inspections are more thorough than HCFA inspections ....
>
> CAP has a uniform set of checklists which its teams use as an approach to inspecting laboratories. These checklists ensure thorough and relatively standardized approach to inspections across the country. Teams are different and inspectors vary in their personal thoroughness and interpretation of certain guidelines, but this is no different than with any inspection group.
>
> The state health departments follow a guideline from HCFA, but also follow standards developed by their individual states. The checklists are therefore varied. Our impression is that the inspections are less stringent, less thorough, and less complete.
>
> The CAP inspection is much more helpful in that it helps us focus on all aspects of our laboratory process. We use the checklist not only for required inspections and self-inspections, but as on-going tools to maintain quality.

Other ACLA members commented that HCFA licensure is easier to obtain than CAP accreditation. CAP inspectors tend to be more consistent, thorough and helpful; they conduct better quality inspections than HCFA.

Question

3. Do you believe that the deemed organizations, the Joint Commission and the CAP, could play a greater role in enforcement of standards of lab quality? If so, what specific recommendations would you have?

Response

All entities involved in certifying, inspecting, and/or offering proficiency testing programs to laboratories should be more diligent in fulfilling their responsibilities; however, with regard to enforcement, ACLA believes that this activity should rest primarily with the federal government. Although states and private organizations should be offered the opportunity to obtain deemed status with regard to the monitoring of lab compliance with federal standards, when problems arise, it should be the federal government that undertakes enforcement. Accordingly, deemed entities should be required to report problems to the government.

Question

4. Do you agree with critics of the CDC's proposed uniform grading system for proficiency testing who argue that it is too lenient and would allow marginal performance to continue under Medicare and CLIA? Would you support a more stringent grading system?

Response

CDC's proposed uniform grading system is too lenient. Satisfactory performance grades should be set somewhere between the CDC proposal and the New York program which is too inflexible in establishing its passing scores. In developing the system, clinical relevance should be considered. For example, an ACLA member reported that it obtained a score of 6.015 on a New York proficiency testing sample with a target value of 6.02. There was no clinical difference between the result obtained by the laboratory and the New York target grade. The new grading system should not be so inflexible that a score which would be acceptable for clinical purposes is considered a failure by a proficiency testing program.

Question

5. At the hearing, Mr. Groome stated that the ACLA would support a requirement that labs document the workloads for

each cytotechnologist and impose some mandatory workload limitations. What would be an appropriate workload limit for cytotechnologists?

Response

Not surprisingly, ACLA members have a variety of views on this subject. Average daily workload guidelines of from 52 to 57 two-slide cases to 75 to 80 one-slide cases have been suggested. Certain ACLA members have proposed an absolute limit of 100 cases a day. Others have recommended adoption of an average of 10,000 cases per cytotechnologist per year. Some ACLA members have found it difficult to offer a precise and appropriate workload limitation standard. Still others feel that the adoption of a workload limitation should be avoided as it would not solve the pap smear problems. ACLA members do agreed that a flat, inflexible, artifically low workload limitation is inappropriate given the variations that occur due to hard cases and easy cases, up days and down days and individual cytotechnologist screening abilities. Moreover, impostion of rigid workload limitations will exacerbate the already critical shortage of cytotechnologists.

Question

6. At the hearing, Mr. Groome stated that the ACLA is opposed to lab personnel moonlighting. Do you have any suggestions for limiting the practice of moonlighting?

Response

A number of ACLA members had a variety of comments on this question. One ACLA member stated as follows:

> Moonlighting: A tough one .... I think we ~~just~~ have to say that the lab must evaluate the performance of all

> techs .... If tech meets performance specs, I don't see how to say you can't moonlight .... Would this mean you can't have overtime and so forth .... I think this would be a big mistake .... Big cytotech shortage, ...

Another ACLA member offered the following observations:

> The cytotechnologist should be certified and it should be a requirement of that certification that the practice is limited to 80-90 slides per day. Employers certainly can control the in-house workload but cannot be expected to be responsible for off-hours activities. It should be noted in this context that we have a crisis in the supply of cytotechs. Now. Any move to correct these problems has to include provision for a crash program of training and certification of qualified individuals.

Another ACLA member suggested a variety of recommendations that might eliminate the need for moonlighting. They were:

a. Adequate hourly salaries for cytotechs.

b. Use both professional certification and the laboratory license rules to prohibit moonlighting.

c. Reopen schools and encourage employers to support students of cytology in order to build a supply, reduce the need to overwork existing qualified individuals.

Laboratories cannot be held responsible for the activities of cytotechnologists after they have left the laboratory facility and the control of the employer. However, laboratory employers can discourage moonlighting and should do so. Moreover, laboratory employers can obtain agreements from cytotechnologist employees not to do more than a prescribed number of pap smears a day. Indeed, such a provision could be made part of the employment agreement between the laboratory and the cytotechnologist.

Question

7. At the hearings, several witnesses expressed strong concern about the practice among some labs of paying

cytotechnologists by the piece rather than on a salaried basis. Do you have any suggestions for limiting this practice?

Response

Piece payment should be discouraged. A number of ACLA members suggested that regulations should be adopted which prohibit piece payment. One ACLA member noted as follows:

> We believe that paying cytotechnologists as salaried employees is the best approach. Where piece rates are used, the rates should be required to be high enough that a cytotechnologist does not have to screen unreasonable numbers of slides to earn a living, and the same limitations on slides/day should apply.

In addition, ACLA members felt that solving the problems referred to in questions 5 and 6 would go a long way towards discouraging piece payment.

Question

8. At the hearings, several witnesses expressed support for required certification testing of cytotechnologists. Would you support a requirement that cytotechnologists be certified through periodic proficiency exams?

Response

ACLA would support such requirements, assuming well defined, equally applied, uniform proficiency standards.

With regard to this question, ACLA members made the following comments:

> Certification through competency-based examinations should be required. Recertification must include examination and continuing education mechanisms, allowing either to qualify the individual.

* * * * * *

> I would support periodic proficiency testing for cytotechnologists for certification .... At least would require an initial certification and no part-time highschool students doing off-site, at home .... would ban at-home/off-site cytotech screening ....

* * * * * *

> We support the mechanism of entry-level certification by competency-based exams. A system of recertification through documented, continuing education and/or examination should be instituted to sustain competency.
>
> Recertification exams could take the form of regionally-based comprehensive sets of actual slides used for tests given twice a year in each region. Elizabeth Plott of CDC ran a "self-assessment" series along these lines some years back. To recertify, each cytotech would need to pass an exam every year. Photomicrographs are not a satisfactory substitute and should not be used.
>
> The primary issue in cytotechnology now is the shortage of qualified personnel. A commitment to allied health education as a whole and cytotechnology, in particular, is needed immediately. ... This shortage is critical now and will be a crisis soon. Certainly any move to limit productivity will precipitate that crisis immediately in some areas.

Other ACLA members suggested recertification every three years or within a reasonable period of time after return to the profession.

ACLA thanks the Subcommittee for the opportunity to submit these supplemental views. We look forward to meeting with the Subcommittee and would be pleased to answer any additional questions it may have.

AMERICAN ASSOCIATION OF BIOANALYSTS
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May 6, 1988

The Honorable Carl Levin, Chairman
The Honorable William S. Cohen,
  Ranking Minority Member
Committee on Governmental Affairs
Subcommittee on Oversight of
  Government Management
Washington, DC 20510-6250

Dear Senators Levin and Cohen:

Thank you for your letter dated 22 April 1988. Following are the responses of the American Association of Bioanalysts (AAB) to your questions:

1. We consider cytotechnology as a subsection of anatomic pathology. The great majority of our members do not perform these procedures and we, therefore, do not offer any suggestions concerning workload limitations for cytotechnologists. According to Senator Brock Adams, half of the errors in Pap smear testing are made by the physician when collecting the specimen. To improve Pap smear testing results, the problem of physician error when collecting the specimen cannot be ignored. Placing the responsibility for reducing the specimen collection error rate on the laboratory will NOT work.

2. See answer to Question #1.

3. AAB supports entry-level proficiency examinations for all clinical laboratory personnel at all levels in the clinical laboratory, including phlebotomist, technician, technologist, supervisor, and director, regardless of educational degrees attained.

   We also recommend that you examine the proficiency requirements for pathologists. After all, not all of the problems within cytology laboratories can be blamed on the cytotechs. Didn't one of your "horror stories" at the March 23-24 hearing involve a pathologist?

The Honorable Carl Levin
The Honorable William S. Cohen
May 6, 1988
Page 2

4. No, unless you intend to limit public employees, e.g., firemen and policemen, from moonlighting.

5. A "direct" bill requirement may alter the discounting practices of some laboratories, but it will also induce the large corporate independent laboratories to shift their discounting practices to the sale of physician office laboratory equipment, reagents and supplies. (Remember that five of the six largest independent clinical laboratories also market POL laboratory equipment, reagents, and supplies).

As stated in our March 24 testimony, financial incentives for Physician Office Laboratory (POL) testing increase the utilization of laboratory services, thereby significantly increasing Medicare outlays for Part B laboratory procedures.

AAB is willing to discuss alternative methods (to a direct billing requirement) of addressing the issue of laboratory discounting practices. If you are interested, we will instruct AAB's Washington representative, Donald Lavanty, to provide additional details.

Sincerely,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Associate Administrator

MSB:js

cc: AAB Board of Directors

american society of internal medicine

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BY HAND

May 5, 1988

Honorable William S. Cohen
Ranking Minority Member
Subcommittee on Oversight of Government
Management
Committee on Governmental Affairs
Room 439, Senate Hart Office Building
United States Senate
Washington, DC 20510-6250

Dear Senator Cohen:

I am pleased, on behalf of the American Society of Internal Medicine (ASIM), to submit the attached responses to your written questions for inclusion in the official record of the Subcommittee's March 23-24 hearing on the issue of quality in clinical laboratory testing.

Please contact Rich Trachtman, director, Department of Federal Affairs, at ASIM if the Society can be of further assistance.

Sincerely,

William R. Smith, MD

William R. Smith, MD
President

1101 VERMONT AVENUE NW • SUITE 500 • WASHINGTON [illegible] PHONE [illegible]

ATTACHMENT

1. What personnel standards does ASIM view as appropriate for the physician office laboratory?

ASIM believes that **physicians who direct the laboratory should be responsible for insuring there are sufficient personnel with adequate training to conduct the work of the laboratory.** The Society believes this should be monitored through a private sector accreditation body such as the Commission on Office Laboratory Assessment (COLA), now being organized by ASIM, the American Academy of Family Physicians and the College of American Pathologists. **As the program is currently envisioned, physicians who direct laboratories will be required to document to the satisfaction of COLA reviewers that laboratory personnel have sufficient training to perform those specific tests for which they are responsible.** On-site inspection by COLA physician-inspectors could also be arranged at the discretion of the COLA board or upon request of the participating physician laboratory director. As the range of tests performed by physician office labs varies greatly, no single personnel standard can be responsive to all situations. Rather, **physician office lab personnel should be trained to perform those tests which they are called upon to perform in a given physician office lab.**

ASIM strongly believes that the Medicare independent lab personnel standards are inappropriate for physician office labs. In particular, pathologists and Ph.Ds in the lab sciences are not necessary to direct physician office labs. Furthermore, there is no need to automatically require physicians to employ medical technologists in their office labs. There is no evidence of a general need for such personnel to assure satisfactory testing results in these labs. Most physicians who run their own office labs would be unable to afford to hire such personnel. Consequently, if standards containing these personnel requirements are imposed on physician office labs, most would be unable to comply, forcing them to cease operation or at least discontinue providing services to Medicare patients.

As a result, patients would be denied many of the benefits that they now obtain through in-office testing. (See ASIM's white paper, the Case for Physician Office Laboratory Testing, which was appended to the Society's March 24 testimony.) For this reason, ASIM looks forward to working with you and your staff to develop legislation containing sensible personnel requirements for physician office labs as discussed above.

2. What has the effect of regulation of physician office labs been on the number and types of POLs operating in those states with regulation? Have POLs been put out of business in these states?

As most states do not currently regulate physician office labs and, in those that do, there are varying levels of regulation, **we cannot offer a generalized response based on ASIM members' experience.**

Current state POL regulation is not as stringent as the Medicare independent lab standards. Particularly, present state regulation does not include personnel standards, see above, that would be unnecessary and inappropriate for physician office labs. **Given the current status of state regulation, the Society is unaware of widespread compliance problems for our members.** Some state regulation differentiates among various types of physician office laboratories according to the nature and type of tests they perform. The Pennsylvania law provides a good model of how this could be done (see the testimony of Josephine Bartola, Director of the Division of Laboratory Improvement for the State of Pennsylvania, given at the Subcommittee's hearing on March 23). **ASIM believes that such a tiered approach, in which the level of regulation is specific to the nature of the testing done in the laboratory, has considerable merit.**

G-BD-2106

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United States Senate
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OVERSIGHT OF GOVERNMENT MANAGEMENT
WASHINGTON, DC 20510-6250

May 20, 1988

Mr. Allen Williams
Administrator
Northern Virginia Doctors Hospital
601 South Carlin Springs Road
Arlington, Virginia 22204

Dear Mr. Williams:

On March 23 and 24, the Subcommittee on Oversight of Government Management held hearings on the federal regulation of clinical laboratories. Testimony at these hearings focused on the current regulatory framework covering independent and hospital labs, as well as on whether the federal government should regulate clinical testing in physicians' offices.

At the hearing, the Subcommittee heard testimony from individuals who have had personal experiences with laboratory testing errors. On March 23, Robert C. Johnson testified about the Pap smear tests of his wife, Janice Johnson, that had been read and reported by your hospital in October 1978 and October 1979. Mrs. Johnson died of cervical cancer on February 23, 1981. At the Subcommittee's hearing, Mr. Johnson was accompanied by his attorney, Daniel Schultz, who also testified on facts that were discovered about this case during the course of litigation.

For your review, we are enclosing Mr. Johnson's written statement. In addition, although the Subcommittee's contract with our reporting company prevents us from sending you a written transcript of the hearing before it is published, you are welcome to view the transcript at the Subcommittee's office in room 442 of the Senate Hart Office Building. We will also provide you with a copy of the printed hearing record when it is available.

Because this case involves your hospital, we have several questions to which we would appreciate your response for the record. You are also welcome to submit any additional comments you may have on this matter.

Questions:

1. It is our understanding your hospital was accredited by the Joint Commission on Accreditation of Hospitals at the time of Mrs. Johnson's case. How recently had your hospital been inspected and accredited by the Joint Commission prior to October 1978 and October 1979? What were the results of the inspections at that time? Were any problems or deficiencies found in the hospital lab? If so, what was the nature of those problems, and were they corrected?

2. At the time of Mrs. Johnson's case, did your hospital follow internal quality controls in addition to those required by the Joint Commission? If so, please describe them. Have there been any changes to your internal quality control procedures since Mrs. Johnson's case?

3. Does your hospital conduct internal inspections in addition to those required by the Joint Commission? If so, how recently had your hospital inspected the lab prior to October 1978 and October 1979? What were the results of the inspections at that time? Were any problems or deficiencies found? If so, what was the nature of those problems, and were they corrected?

4. Mrs. Johnson's Pap smears were reviewed by Dr. Henrietta Tong Nguyen. Dr. Tong earned her medical degree in Viet Nam, was board certified in anatomical pathology but not clinical pathology, and had some limited training in reviewing Pap smears. At the time of Mrs. Johnson's case, did your hospital have any requirements for lab personnel who review Pap smears? If so, did Dr. Tong meet those requirements? Were your lab personnel required to be tested as to their capabilities to perform the tests they are directed to perform? Was Dr. Tong tested for her competency? What level of supervision did your hospital require of lab personnel who review Pap smears? Have any of these personnel or supervisory requirements changed since the time of Mrs. Johnson's case?

5. Is Dr. Tong still employed at your hospital? If not, when did she leave the hospital's employ and for what reason(s)?

6. It is my understanding that neither of Mrs. Johnson's Pap smears -- which were classified as "Class II" -- were reviewed by Dr. Tong's supervisor or lab director. At the time of Mrs. Johnson's case, did your hospital have any

requirement that Pap smears classified as "Class II" be doublechecked by a supervisor? Does it currently have such a requirement?

7. When and how did your hospital become aware of the errors made in reviewing Mrs. Johnson's Pap smears? Have any changes been implemented by your hospital which would reduce the possibility of errors in Pap smear reviews?

8. Did the Joint Commission require any changes to hospital policies or practices after Mrs. Johnson's case?

We would appreciate a response to these questions by June 7. Please send your response to the Subcommittee on Oversight of Government Management, SH-442, Washington, D.C 20510. If you have any questions, please contact Mary Gerwin (224-5538) or Allie Giles (224-3682) of the Subcommittee staff.

Sincerely,

Carl Levin

Carl Levin
Chairman

William S. Cohen
Ranking Minority Member

CL:WSC:mbg

Northern Virginia
Doctors Hospital

June 13, 1988

The Honorable William S. Cohen
United States Senate
Committee on Governmental Affairs
Subcommittee on Oversight of Government
Management
Washington, DC 20510-6250

Dear Senator Cohen:

We are responding to your letter of May 20, 1988 which asks questions regarding a pap smear performed in 1978, nearly a decade ago. Since then the hospital has changed ownership twice, the pathologists at the time are no longer under contract with the hospital, and there is now a shortage of people still here who are familiar with the incident due to the time that has elapsed. Nevertheless we will attempt to provide answers to your questions.

Question #1

How recently had your hospital been inspected and accredited by the Joint Commission prior to October 1978 and October 1978? What were the results of the inspections at that time? Were any problems or deficiencies found in the hospital lab? If so, what was the nature of those problems, and were they corrected?

Answer

The hospital had been inspected by the JCAH on March 16 and 17, 1978. The results of all JCAH inspections prior to 1980 are not available. Note that Janice Johnson's Pap smears were reviewed under the auspices of the Seven Corners Medical Lab which was a satellite facility to the Northern Virginia Doctors Hospital. This lab was not inspected by the JCAH until 1980.

Question #2

At the time of Mrs. Johnson's case, did your hospital follow internal quality controls in addition to those required by the Joint Commission? Have there been any changes to your internal quality control procedures since Mrs. Johnson's case?

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Arlington, Virginia 22204-1096
Telephone (703) 671-1200

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Answer

At the time of Mrs. Johnson's case, the hospital Pathology Department was staffed with two full time pathologists who were Board certified in anatomic and clinical pathology and a part-time pathologist who was Board certified in anatomic pathology. JCAH requirements at that time stated that at least 10% of all Pap smears that are read by a cytotechnologist be reviewed by a pathologist as a quality control measure. Board certification in anatomic pathology requires training in cytology. One hundred percent of Pap smears were read in the first instance by a Board certified pathologist during the time in question (October 1978-October 1979), thereby exceeding JCAH requirements by a factor of 10. As of our 1987 inspection by JCAH, certification by JCAH requires a documented quality assurance program in the Department of Pathology which includes cytology. Our program includes double-checking of cytology and surgical pathology cases by two staff pathologists as well as referral of problem cases to outside reference centers.

Question #3

Does your hospital conduct internal inspections in addition to those required by the Joint Commission? If so, how recently had your hospital inspected the lab prior to October 1978 and October 1979?

Answer

The hospital laboratory is under daily supervision by the Medical Director. Ongoing review of quality control in the hospital lab by the two pathologists is documented daily. No records of in-house hospital inspections are present from that time period (October 1978 and October 1979).

Question #4

At the time of Mrs. Johnson's case, did your hospital have any requirements for lab personnel who review Pap smears? Did Dr. Tong meet those requirements? Were your lab personnel required to be tested as to their capabilities to perform the tests they are directed to perform? What level of supervision did your hospital require of lab personnel who review Pap smears? Have any of these personnel or supervisory requirements changed since the time of Mrs. Johnson's case?

Answer

Minimal requirements to screen Pap smears at that time were that a person be a college graduate, complete a 2-year internship and to pass the ASCP registry exam for cytotechnologists (see attachment). Dr. Tong exceeded these requirements. She was a college graduate, She completed four years of medical school in Saigon. She completed a four-year residency program in anatomic and clinical pathology at Doctors Hospital and Armed Forces Institute of Pathology in Washington, DC. She was Board-eligible in anatomic pathology in December 1974 and passed the American Board of Anatomic Pathology in May 1978 according to records on file in the hospital. The American Board of Anatomic Pathology tests for competence in cytology. Dr. Tong had "supervisory" level training. Lab personnel are hired for a provisional period during which they are supervised and competence in their duties must be documented. Note that Dr. Tong was not a hospital employee but a physician who was subcontracted to perform pathology services. Dr. Tong was tested for competence by the American Board of Anatomic Pathology. She was evaluated by the Medical Director of the Lab as to her competence in all areas of anatomic pathology. The only restriction placed on her was that she was not to review brain biopsies independently. The hospital required at least 10% of all Pap smears to be reviewed by a person with training at the level of a physician who is Board-certified in anatomic pathology (i.e., a supervisor). Dr. Tong's credentials qualified her as a supervisor. Supervisory requirements have not changed since the Johnson case. Documentation of all quality assurance activities is performed as required by JCAH. All cases including cytology which are double-checked by pathologists are recorded as part of the monthly quality assurance report to the hospital from the Chief Pathologist. This documentation began in February 1987. Specific reference to Pap smears was begun in April 1988.

Question #5

Is Dr. Tong still employed at your hospital?

Answer

Doctor Tong was never a hospital employee. Doctor Tong no longer works in the Department of Pathology. She is a physician in general practice on the hospital staff.

Question #6

At the time of Mrs. Johnson's case, did your hospital have any requirement that Pap smears classified as "Class II" be double-checked by a supervisor? Does it currently have such a requirement?

Answer

All Pap smears were read in the first instance by physicians (i.e., supervisory personnel). Problem cases were double-checked by physicians as is routine practice, however no method of documentation of these activities was in place at that time. Cytotechnologists or "screeners" are not used in our laboratory. All Pap smears are read by Board-certified physicians with the subspecialty of anatomic pathology. We continue to have problem cases double-reviewed. Documentation of these activities began in February 1987. Specific references to Pap smears are included in our quality assurance reports as of April 1988.

Question #7

When and how did your hospital become aware of the errors made in reviewing Mrs. Johnson's Pap smears? Have any changes been implemented by your hospital which would reduce the possibility of errors in Pap smear reviews?

Answer

The result of a certical biopsy which was taken on 2/22/80 was communicated to the laboratory director. At that time the laboratory director retrieved from the files Pap smear reports and Pap smear slides for Mrs. Johnson which were done on 2/3/85, 9/13/77. 10/19/78 and 10/4/79. These slides were reviewed by an independent outside reviewer who agreed with the interpretation of Class II (atypical cells present; no malignant cells) of the 1975 and 1977 Pap smears. He felt that the 1978 and 1979 Pap smears should have been classified as Class III (suspicious for cancer) and Class IV (highly suspicious for cancer), respectively. Review of the case also indicated that Pap smear reports dating back to 1975 had written comments on them suggesting to the requesting physician that much more frequent gynecological follow-up be given to Mrs. Johnson, much more follow-up than she eventually received. Note that none of her Pap smears were read as Class I (normal). This authority noted that "the normal procedure with Class II Pap smear is to treat the inflammatory activity and recheck the cytology in three to six months. Not to treat and recheck is to invite the lesion to become more severe". Had the suggested pattern of follow-up indicated on the Pap smear reports been undertaken, Mrs. Johnson would be alive today. Note that after the laboratory director became aware of Mrs. Johnson's cancer, he rescreened every Pap smear which Dr. Tong had ever read at Northern Virginia Doctors Hospital. At the time of the Janice Johnson case, the lab at Northern Virginia Doctors Hospital received approximately 165 Pap smear cases per week from the Seven Corners Medical Lab. Note that some popular press reports about the Janice Johnson case reported in error that 300 cases were read per day. Since that time the Seven Corners Medical Lab has ceased to exist. The volume of Pap smears read at our Laboratory has dropped dramatically. In 1986, only 31 Pap smear cases were reviewed at our hospital, all by Board-certified pathologists. An identical number was reviewed in 1987, again all by Board-certified pathologists and so far in 1988 there have been only eight Pap smear cases reviewed. Of the eight Pap smears reviewed so far this year, one was double-checked by both pathologists. All Pap smears in 1988 have been Class I. Cytology, including Pap smears, is included in the quality assurance report to the hospital from the Chief Pathologist.

Question #8

Did the Joint Commission require any changes to hospital policies or practices after Mrs. Johnson's case?

Answer

The JCAH made many recommendations in regard to hospital policies and practices in their inspection of 1980 and 1981. No suggestions relating to Pap smears were made (see attachment).

We hope that we have been able to respond satisfactorily to the questions raised in your letter. It has not been an easy task to undertake given the time factor involved - many things change in 10 years' time. If you have any further questions we would be pleased to attempt to provide answers.

Very truly yours,

NORTHERN VIRGINIA
DOCTORS HOSPITAL

Allen Williams

Allen Williams
Administrator

AW:ph

Enclosures as stated.

Laboratory Summation Conference - J.C.A.H.

March 16, 1981

The very first recommendation I have is in the Microbiology area. I do feel that the department is very short spaced. There is an inadequate amount of space in the room as well as a lack of storage space. To have three people working in such a small room and to do the volume of work that you have, I think you should really take a look at that and see possibly a different storage area or maybe enlarging the room.

The next recommendation is the satellite laboratory at Seven Corners. We have a standard which states that flammable liquids shall not exceed a two days working supply or that you must have it in one of the flammable storage cabinets. Presently you are storing under the sink, if I recall correctly, and there is a little bit too much there for just everyday storage.

I should stop at this point also and add that on the last survey you had 34 recommendations. Of these 34 I must repeat three recommendations. The others have all been satisfactorily taken care of.

The next recommendation is a previous recommendation that is being repeated. We state that the request for inpatient and outpatient laboratory work as well as the accession record must include the date and the time of collection. I am specifically referring here to those specimens that are collected by nursing personnel for the urinalysis department. When we reviewed the slips, I would say about 50% of the slips did not have times on, so that is something that will come back under the laboratory recommendations but it really relates to nursing service.

My next recommendation is under quality control section. We look to see that you are currently participating in a proficiency testing program for each discipline of the clinical laboratory and that you successfully participate. I have noted in my report that for 1980 you did not participate in anything for the hepatitis testing, but I have seen a purchase order where in 1981 this will be taken care of. Whether or not that will come back to you in writing, will be left up to our central office. It may come back in case something happens to the program and you really don't participate this year, but that is tentative as to whether or not you will receive that in writing.

Also, we look to see that for laboratory equipment and instruments that you maintain certain records. Now the records that I am referring to are the temperature records; in this instance for the Blood Bank it is necessary that you document the temperatures for everything in there including weekends. Monday through Fridays you did fairly well, but weekends were kind of lacking. In the area of Hematology, that was a little sporatic. I think you need to pay closer attention to daily documentation for temperatures and in the Chemistry area also for the refrigerators.

I have nothing specifically for the anatomic surgical pathology side or for cytology.

Summation (cont'd)

The next recommendation I have is in the area of Blood Bank. It is necessary also that you document the daily inspection of the units of blood for possible bacterial contamination or hemolysis on a daily basis. The specific recommendation here is being made for the lack of documentation on weekends.

The next recommendation is also in the area of Blood Bank. It relates to your quality control documentation. Here again, it is necessary that you do do your quality control of your reagents on weekends and keep the documentation for such. Monday through Fridays it seemed to be fine but the weekends were a little bit lacking.

The next area that I have is Bacteriology. I have a previous recommendation here to repeat. On each day of use, biological reagents, solutions and antisera should be quality controlled and you should maintain your documentation for such. The specific recommendation that I am making will be for the lack of the records or documentation for the antisera that you are using for any typings that you are doing, as well as the X and the V factors, the reagent strips that you would be using there. Also the API reagents must be tested on a daily basis, not on a weekly basis and the A test for the autoclave; that must be done on a weekly basis rather than a monthly basis as you are presently doing.

The next recommendation is also for Bacteriology. Each batch of media must be tested concurrently with its use with known organisms as well as tested for sterility. Recommendations specifically for the commercial media that you are buying, you are not repeating or not doing your own quality control for those media. Also for the broths that are being used in the department you have no quality control records for those and the media that you use very infrequently; whenever you do use the media you must quality control it and keep documentation of the results.

In the area of Hematology I have one recommendation. We have a standard that states that reference materials and methods shall be tested on each day of use against known standards or controls within a range of different patient values. Presently you are not running the various levels of control on each day, so theoretically on a day you may be testing a low range as well as a midpoint range and on another day you may be testing a high and a midpoint. But, its on each day that we are looking for testing in all ranges.

That is the extent of my recommendations. Are there any questions about anything or any comments? I also do want to note that we did have a few onsite corrections which I think have been very helpful. It shows me that you people are really interested in what you are doing and if there was anything that could be corrected you were more than willing to do it while I was here. I thank you all for your cooperation and your participation in this survey.

Job Description
Medical Cytotechnologist

Qualifications:

The cytotechnologist should have the ASCP registry in cytology or be eligible for the registry or should have equivalent credentials. The cytotechnologists' duties and responsibilities will include but will not be limited to the following:

Duties:

1. Microscopic screening of all cytology slides.
2. Selecting all abnormal cytologies for review by the pathologist.
3. Maintaining the quality control program.
4. Establishing and maintaining a file of all abnormal smears to include but not to be limited to the following:
   a. all Class III gyn cytologies and above
   b. information on why requests for repeat smears have been made
   c. interesting cases of medical curiosity or certain physician interest
5. Obtain follow-up information on all Class III's and above after a minimum of six months wait.

In addition, the cytotechnologist will not necessarily have to manually prepare cytology specimens. This cytotechnologist should have demonstrated proficiency in collecting, preparing and staining cytology material.

Responsibility:

Cytotechnologist will be directly responsible to the pathologist and assistant pathologist and conform to standards: Professional attributes.

Approved

Ray L Hemness

R.L. Hemness
Administrator

Purissima Roberts

2/81

Final

CDC Proposal
for a
Uniform Proficiency Testing Program
for
Medicare-Certified Laboratories
and
Laboratories Licensed Under the
Clinical Laboratories Improvement Act of 1967

Developed by
Division of Assessment and Management Consultation
Training and Laboratory Program Office

December 1987

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
Atlanta, Georgia 30333

PREFACE

Each year the medical community relies more heavily on laboratory test results, increasing the need for better methods to assure that tests are performed properly. The predominant method used for demonstrating the performance capabilities of laboratories is "mailed proficiency testing."

Proficiency testing provides an external assessment of the quality of laboratory performance. As such, it serves as an indicator of a need for standardizing methodologies and materials, for providing training and education in specific areas, and for improving general and individual laboratory performance. It can also provide educational opportunities and indicate that laboratory performance is adequate to meet the intended use.

For proficiency testing to be effective, the proficiency testing program providers must assure the quality of test samples, appropriately evaluate the testing results, and identify performance problems in a timely manner. The program user must test the samples as if they were patient specimens and take corrective action when problems are identified. Professional organizations, manufacturers, and governmental agencies must respond to needs for better methodologies and materials and for training and educational programs. Administrators of regulatory programs must apply appropriate criteria in evaluating individual laboratory performance but must not hesitate to take action to restrict a laboratory's ability to offer service when patient care may be jeopardized and reasonable efforts to improve the quality of testing have failed.

In this document, we attempt to define a proficiency testing program that could be used as the national standard for evaluating the performance of laboratories that are Medicare certified or are licensed under the Clinical Laboratories Improvement Act of 1967 (CLIA '67). Successful implementation of this program depends on the cooperation of all the groups mentioned above.

The Uniform Proficiency Testing Program as defined in this document is intended to be used as a regulatory program. Several current providers of proficiency testing programs could furnish the quarterly mailed samples and perform the initial evaluation of performance. Proficiency testing program providers, the Health Care Financing Administration (HCFA), or State agencies could determine acceptable performance for samples distributed by these providers. Any group could undertake educational and improvement efforts made on the basis of laboratory performance to correct laboratory errors before they require regulatory action. The HCFA or designated State agencies could take regulatory action to deny licensure or reimbursement to laboratories with sustained unacceptable performance.

Members of the Centers for Disease Control (CDC) Task Force on a Uniform Proficiency Testing Program wish to thank all who commented on the proposal. Some comments were detailed and specific and others were general, but all were viewed as constructive. Although all comments were carefully considered, not all could be accommodated.

Written comments concerning this proposal that were received by CDC before November 15, 1987, were considered for inclusion in the final draft, which will be submitted to HCFA.

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CDC Proposal for a Uniform Proficiency Testing Program for Medicare-Certified Laboratories and Laboratories Licensed Under the Clinical Laboratories Improvement Act of 1967

1.0 INTRODUCTION

This is the final version of a proposal that was developed by the CDC Uniform Proficiency Testing Program Task Force in response to a request from the Health Care Financing Administration (HCFA) to provide a proficiency testing program that could be applied to both those laboratories that receive Medicare reimbursement and those that are interstate licensed under the Clinical Laboratories Improvement Act of 1967 (CLIA '67). This proficiency testing program, when adopted by the HCFA and published as a regulatory change, would establish basic criteria for the quality of laboratory performance required by HCFA for both types of laboratories.

The Task Force is grateful to everyone who has offered comments on the earlier versions of this proposal. The final CDC proposal was made after careful consideration of all comments. Comments that were not incorporated in the final proposal are listed in an appendix, along with the Task Force response to the comment.

Although specific requirements for a proficiency testing program were included in the CLIA '67 regulations (Federal Register, Vol. 33, No. 253, Tuesday, December 31, 1968, Subpart E), minimally acceptable requirements for Medicare-certified laboratories have never been described by the Secretary of the Department of Health and Human Services. As a consequence, States have offered or approved proficiency testing programs that vary considerably in their degree of challenge. The following materials describe the process for approval of a proficiency testing program, the essential components of an acceptable program, and an implementation plan for the Uniform Proficiency Testing Program.

2.0 SCOPE

Our initial proposal was intended to serve as a starting point for phasing in a uniform proficiency testing program for laboratories that are Medicare certified or are licensed under CLIA '67. The focus was on assessing the quality of those laboratory tests whose results, if in error, are widely used or carry a moderate-to-high risk of death or severe injury to the patient, or both. It was always our intention to include additional tests as soon as they were judged ready for a national evaluation in a regulatory context. It is also our intention to exclude from the national uniform program those test areas for which no performance problems are evident. While uniform proficiency testing is being phased in, the present requirement that laboratories participate successfully in a State-operated or State-approved proficiency testing program covering all specialities or subspecialities for which the laboratory is approved to perform tests will be in effect. This will permit States to continue to monitor laboratory performance in areas that are not yet part of the uniform proficiency testing program and allow any group to offer an educational or improvement program in these or other areas. Even when the uniform program is in effect, a state may choose to offer or require a more stringent program.

purpose of the program is to identify laboratories whose level of performance constitutes a threat to public health and not to provide educational benefits or to establish an optimum in laboratory performance.

3.0 DEFINITIONS

Sample -	A vial, a slide, or other unit that contains material to be tested by program participants. When possible, samples should be of human origin.
Challenge -	For quantitative tests, a challenge is defined as an assessment of the amount of substance or analyte present in a sample. For qualitative tests, a challenge is the determination of the presence or the absence of an analyte, organism, or substance in a sample.

4.0 CRITERIA FOR ACCEPTABLE PROGRAMS

A proficiency testing program that is acceptable to the Secretary for use to certify or license federally monitored laboratories must meet certain requirements. These include: (1) the resources needed to provide a statewide or nationwide program issuing reports to laboratories and regulatory agencies on a timely basis; (2) the technical knowledge required to prepare and distribute samples using rigorous quality control to assure that samples are homogeneous and will be stable within the time frame for analysis by survey participants; (3) a scientifically defendable process for determining the correct answer for each challenge offered by the program; and (4) the provision of an annual program of sufficient challenge and frequency to establish whether or not a laboratory has met minimum performance requirements as described by the Secretary. Providers of partial proficiency testing programs must also meet these criteria before their programs can be deemed acceptable by the Secretary. Requirements for program providers and for their laboratory participants in specific laboratory areas are listed below.

5.0 PROGRAM DESCRIPTIONS BY CATEGORY

The categories listed are those used by the Medicare certification program. It is recognized that these categories may consist of several surveys as they are currently provided by proficiency testing programs.

5.1 Chemistry

A. Program Content and Frequency of Challenge

In the area of chemistry, an approved program would provide a minimum of two samples per quarter. The annual program would provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The minimum number of challenges for each analyte or test per quarter is listed below. Note that an analyte need not be present in every sample; therefore, the number of challenges does not always equal the number of samples.

Alanine Aminotransferase (ALT/SGPT)	2
Albumin	2
Alkaline Phosphatase	2
Amylase	2
Aspartate Aminotransferase (AST/SGOT)	2
Bilirubin, Total	2
Blood Gas and pH	2
Calcium, Total	2
Chloride	2
Cholesterol, Total	2
Cholesterol, High Density Lipoprotein	1
Cortisol	2
Creatine Kinase	2
Creatine Kinase, Isoenzymes	1
Creatinine	2
Glucose	2
Iron, Total	2
Lactate Dehydrogenase (LDH)	2
LDH Isoenzymes	1
Magnesium	2
Potassium	2
Sodium	2
Thyroxine	2
Triglycerides	2
Thyroid-Stimulating Hormone	2
Urea Nitrogen	2
Uric Acid	2

Chemistry (Other)	Analyte or Test	Challenges/Quarter
	Alcohol (Blood)	2
	Blood Lead	2
	Carbamazepine	1
	Digoxin	1
	Ethosuximide	1
	Gentamicin	1
	Lithium	1
	Phenobarbital	1
	Phenytoin	1
	Primidone	1
	Procainamide (and Metabolite)	1
	Quinidine	1
	Theophylline	1
	Valproic Acid	1

analyte or test response will be evaluated on the basis of the accuracy of the response. For qualitative chemistry tests or analytes, the correct response for each challenge is determined by an 80% or better agreement among at least 10 referee or all participating laboratories. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality.

For quantitative chemistry tests or analytes, the correct response for each challenge is determined by the distance of the response from the target value. The target value is the mean of all responses after removal of outliers (those responses greater than 3 standard deviations (SD) from the original mean) or is the mean of groups of 20 or more participants that use the same methodology (to be used only when the method bias results in a skewed distribution of responses). If the method group is less than 20 participants, the group is evaluated against the overall mean after outlier removal unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate. A target value may also be determined using methodology of known accuracy such as a definitive reference, or comparative method. After the target value has been established for each response, the appropriateness of the response determined by using either fixed criteria (percentage difference from the target value) or the number of SDs the response differs from the target value. The evaluation scheme for each response is listed in the next section.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program evaluations of performance should be based on the entire set of samples and not the minimum number.

Analyte or Test	Criteria for Acceptable Performance
Alanine Aminotransferase (ALT/SGPT)	Target Value ± 20%
Albumin	Target Value ± 10%
Alkaline Phosphatase	Target Value ± 3 SD
Amylase	Target Value ± 3 SD
Aspartate Aminotransferase (AST/SGOT)	Target Value ± 10%
Bilirubin, Total	Target Value ± .3 mg/dL or 20% (greater term)
Blood Gas pO2	Target Value ± 3 SD
pCO2	Target Value ± 3 mmHg or 8% (greater)
pH	Target Value ± .04
Calcium, Total	Target Value ± .8 mg/dL
Chloride	Target Value ± 5%
Cholesterol, Total	Target Value ± 15%
Cholesterol, High Density	Target Value ± 3 SD
Cortisol	Target Value ± 25%
Creatine Kinase	Target Value ± 3 SD
Creatine Kinase Isoenzymes	MB Elevated (+ or -) or Target Value ± 3 SD
Creatinine	Target Value ± .2 mg/dL or 7% (greater term)
Glucose	Target Value ± 10%
Iron, Total	Target Value ± 20%
Lactate Dehydrogenase (LDH)	Target Value ± 20%
LDH Isoenzymes	LDH1/LDH2 (+ or -) or Target Value ± 3 SD
Magnesium	Target Value ± 25%
Potassium	Target Value ± .3 mmol/L
Sodium	Target Value ± 3 mmol/L or ± 4 mmol/l if Target Value is above 150 mmol/L
Thyroxine	Target Value ± 2 SD
Triglycerides	Target Value ± 3 SD
Thyroid-Stimulating Hormone	Target Value ± 3 SD
Urea Nitrogen	Target Value ± 2 mg/dL or 9% (greater)
Uric Acid	Target Value ± 17%
Alcohol, Blood	Target Value ± 25%
Blood Lead	Target Value ± 15% or 6 mcg/dL (greater)
Carbamazepine	Target Value ± 25%
Digoxin	Target Value ± 20% or ± .2 ng/mL (greater term)
Ethosuximide	Target Value ± 20%
Gentamicin	Target Value ± 25%
Lithium	Target Value ± .2 mmol/L
Phenobarbital	Target Value ± 20%
Phenytoin	Target Value ± 25%
Primidone	Target Value ± 25%
Procainamide	Target Value ± 25%
Quinidine	Target Value ± 25%
Theophylline	Target Value ± 25%
Valproic Acid	Target Value ± 25%

For two of the three [illegible] or surveys, a laboratory must not have a test or analyte for which all results have been unacceptable and must maintain a cumulative average score of 70% of acceptable responses for the three events or surveys in any recognized reimbursement or licensure speciality. Failure to participate in a survey, except when patient specimen testing is suspended, will result in a score of 0 for the survey.

5.2 Hematology

A. Program Content and Frequency of Challenge

In the area of hematology an approved program would provide a minimum of two samples per quarter. The annual program would provide samples that cover the full range of values that would be expected in patient specimens. The minimum number of challenges for each analyte or test per quarter is listed below.

Program Content and Frequency of Challenge

Hematology (Routine)	Analyte or Test	Challenges/Qu
	White Cell Differential and/or Cell ID	2
	Erythrocyte Count	2
	Hematocrit (Packed Cell Volume)	2
	Hemoglobin	2
	Leukocyte Count	2
	Platelet Count	2
Hematology (Coagulation)		
	Fibrinogen	2
	Partial Thromboplastin Time	2
	Prothrombin Time	2

B. Evaluation of Analyte or Test Performance

Analyte or test responses will be evaluated on the basis of the accuracy of the response. For qualitative hematology tests or analytes, the correct response for each challenge is determined by an 80% or better agreement among at least 10 referee or all participating laboratories. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality.

For quantitative hematology tests or analytes, the correct response for each challenge is determined by the distance of the response from the target value. The target value is the mean of all responses after removal of those responses greater than 3 standard deviations (SD) from the original mean or is the mean of groups of 20 or more participants that use the same methodology (to be used only when the method bias results in a skewed distribution of responses). If the method group is less than 20 participants, the group is evaluated against the overall mean after outlier removal unless acceptable scientific reasons are available to indicate that such an evalu methodology of known accuracy such as a definitive [illegible] or comparative method. After the target value has been [illegible] for each response, the appropriateness of the response is determined using either fixed criteria (percentage difference from the target value) or the number of SDs the response differs from the target value. The evaluation scheme recommended for each response is listed in the next section.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Determination of Appropriate Response

Analyte or Test	Criteria for Acceptable Performance
Cell Identification	80% Consensus on Identification
White Cell Differentiation	Target ± 3 SD
Erythrocyte Count	Target ± 3 SD or 6% (lesser)
Hematocrit	Target ± 3 SD or 6% (lesser)
Hemoglobin	Target ± 3 SD or 5% (lesser)
Leukocyte Count	Target ± 3 SD or 10% (lesser)
Platelet Count	Target ± 3 SD or 25% (lesser)
Fibrinogen	Target ± 3 SD
Partial Thromboplastin Time	Target ± 3 SD or ± 15% (greater)
Prothrombin Time	Target ± 3 SD or ± 15% (greater)

D. Criteria for Acceptable Performance

For two of the three most recent testing events or surveys, a laboratory must not have a test or analyte for which all results have been unacceptable and must maintain a **cumulative average score of 70%** of acceptable responses for the three events or surveys for any recognized reimbursement or licensure category. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

5.3 Immunohematology

A. Program Content and Frequency of Challenge

In immunohematology, three types of laboratories are recognized:

1. Those that perform ABO and/or Rh typing, but do not perform irregular antibody detection or identification.
2. Those that perform ABO and/or Rh typing, compatibility testing, irregular antibody detection, and crossmatching, but do not perform antibody identification.
3. Those that perform ABO and/or Rh typing, compatibility testing, irregular antibody detection, and crossmatching, and also perform antibody identification.

In the area of immunohematology, an approved program would require a minimum of two samples per quarter. The annual program [illegible] samples that cover the full range of interpretation that would be expected in patient specimens. The minimum number of challenges for each analyte or test per quarter is listed below. Note that an analyte need not be present in every sample; therefore, the number of challenges does not always equal the number of samples.

Program Content and Frequency of Challenge

Analyte or Test	Challenges/Quarter
ABO Grouping	2
Rh Typing	2
Antibody Detection	2
Antibody Identification	2
Crossmatch Compatibility	2

B. Evaluation of Analyte or Test Performance

Analyte or test responses will be evaluated on the basis of the accuracy of the response. For immunohematology tests or analytes, the correct response for each challenge is determined by a 90% or better agreement among at least 10 referee or participant laboratories. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality. The evaluation scheme recommended for each response is listed in the next section.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Determination of Appropriate Response

Analyte or Test	Criteria for Acceptable Performance
ABO Grouping	100% Accuracy on 95% Consensus
Rh Typing	100% Accuracy on 95% Consensus
Antibody Detection	80% Accuracy on 90% Consensus
Antibody Identification	80% Accuracy on 90% Consensus
Crossmatch Compatibility	100% Accuracy on 95% Consensus for Incompatible Crossmatches and No More Than One False Incompatible For Compatible Crossmatches in Three Surveys or Testing Events

D. Criteria for Acceptable Performance

A laboratory must maintain a score of 100% acceptable responses for grouping, typing, and crossmatch compatibility for incompatible crossmatches because of the potential of a lethal mismatch should an error occur in these procedures. More than one incorrect incompatible in three surveys or testing events is unacceptable for identification, [redacted] [illegible] the three most recent testing events or surveys for any recognized reimbursement or licensure specialty. Sample scores are averaged to determine the survey score. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

5.4 Immunology (Serology)

A. Program Content and Frequency of Challenge

In the area of immunology, an approved program would provide a minimum of two samples per quarter (except in the special case of syphilis serology, where five samples are required). The annual program would provide samples that cover the full range of reactivity from highly reactive to nonreactive. The minimum number of challenges for each analyte or test per quarter is listed below. Note that an analyte need not be present in every sample; therefore, the number of challenges does not always equal the number of samples.

Program Content and Frequency of Challenge

Analyte or Test	Challenges/Quarter
Alpha-1 antitrypsin	1
Alpha-fetoprotein	1
Antinuclear Antibody	1
Antistreptolysin O	1
Anti-Human Immunodeficiency Virus (HIV)	2
Complement C3	1
Complement C4	1
Hepatitis Markers (HBsAg, anti-HBc, HBeAg)	2
IgA	1
IgE	1
IgG	1
IgM	1
Infectious Mononucleosis	1
Rheumatoid Factor	1
Rubella	2
Syphilis	5

B. Evaluation of Analyte or Test Performance

Analyte or test responses will be evaluated on the basis of the accuracy of the response. For qualitative immunology tests or analytes, the correct response for each challenge is determined by an 80% or better agreement among at least 10 referee laboratories or all participant laboratories; the proficiency testing program provider should indicate the minimum concentration that will be considered as indicating a positive response. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality.

each challenge is determined by the distance of the response from the target value. The target value is the mean (or median or mode) of all responses after removal of those responses greater than 3 standard deviations from the original mean or is the mean of groups of 20 or more participants that use the same methodology (to be used only when the method bias results in a skewed distribution of responses). After the target value has been established for each response, the appropriateness of the response is determined by using either fixed criteria or the number of standard deviations the response differs from the target value. The evaluation scheme recommended for each response is listed in the next section.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Determination of Appropriate Response

Analyte or Test	Criteria for Acceptable Performance
Alpha-1 antitrypsin	Target Value ± 3 SD
Alpha-fetoprotein	Target Value ± 3 SD
Antinuclear Antibody	Target Value ± 1 dilution or (+ or -)
Antistreptolysin O	Target Value ± 1 dilution or (+ or -)
Anti-Human Immunodeficiency Virus	Reactive or Non-Reactive
Complement C3	Target Value ± 3 SD
Complement C4	Target Value ± 3 SD
Hepatitis (HBsAg, anti-HBc, HBeAg)	Reactive (Positive) or Non-Reactive
IgA	Target Value ± 3 SD
IgE	Target Value ± 3 SD
IgG	Target Value ± 3 SD
IgM	Target Value ± 3 SD
Infectious Mononucleosis	Target Value ± 1 dilution or (+ or -)
Rheumatoid Factor	Target Value ± 1 dilution or (+ or -)
Rubella	Target Value ± 1 dilution or (+ or -)
Syphilis	Target Value ± 1 dilution or (+ or -)

D. Criteria for Acceptable Performance

For two of the three most recent testing events or surveys, a laboratory must not have a test or analyte for which all results have been unacceptable and must maintain a cumulative average score of 80% of acceptable responses in the three testing events or surveys for any recognized reimbursement or licensure category. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

5.5 Microbiology

Bacteriology

A. Program Content and Frequency of Challenge

1. Those that only interpret gram stains, or that perform primary inoculation, or that use direct antigen techniques to detect an organism or that perform any combination thereof.

2. Those that isolate aerobic and anaerobic bacteria from mixed bacterial populations and perform limited identification and/or perform antimicrobial susceptibility tests on selected microorganisms isolated. They may or may not use direct antigen techniques to identify an organism.

3. Those that are able to identify aerobic and anaerobic bacteria from mixed bacterial populations to both genus and species in most instances and perform antimicrobial susceptibility tests on the microorganisms isolated. They may or may not use direct antigen techniques to identify an organism.

In the area of bacteriology, an approved program would provide a minimum of two samples per quarter. An annual program must include bacterial species that are representative of the six major groups of bacteria: (1) anaerobes, (2) *Enterobacteriaceae*, (3) gram-positive bacilli, (4) gram-positive cocci, (5) gram-negative cocci, and (6) miscellaneous gram-negative bacteria. Approved program providers will be required to furnish a description of samples that they plan to include in their annual program during each calendar year. At least 50% of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens and organisms commonly occurring in patient specimens or that are opportunistic pathogens should be included periodically in the program.

Two types of samples should be included in the program:

1) Those requiring laboratories to report only organisms that they consider to be a significant pathogen that is clearly responsible for a described illness. The reportable isolates will be determined by the program provider. Antimicrobial susceptibility may be requested for the isolate.

2) Those requiring laboratories to report all organisms present. Samples should contain multiple organisms frequently seen in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immunocompromised patients. The reportable isolates will be determined by the program provider.

Both types of sample should meet the 50% mixed culture criterion.

Example Program

Organism

Anaerobes

Bacteroides fragilis group
Clostridium perfringens
Peptostreptococcus anaerobius

Enterobacteriaceae

Klebsiella pneumoniae
Salmonella typhimurium
Serratia marcescens
Shigella sonnei
Yersinia enterocolitica

Gram-positive bacilli

Listeria monocytogenes
Corynebacterium sp. CDC gp JK

Gram-positive cocci

Staphlyococcus aureus
Streptococcus Group A
Streptococcus Group B
Streptococcus Group D (S. bovis and enterococcus)
Streptococcus pneumoniae

Gram-negative cocci

Branhamella catarrhalis
Neisseria gonorrhoeae
Neisseria meningitidis

Miscellaneous gram-negative bacteria

Campylobacter jejuni
Haemophilis influenzae Type B

For Antimicrobial Susceptibility Testing, at least one sample per quarter should be provided that includes gram-positive or gram-negative strains that are susceptible or resistant to the common antimicrobial agents.

B. Evaluation of Performance

Responses will be evaluated on the basis of the accuracy of the response. The correct response for each sample is determined by an 80% or better consensus among at least 10 referee or all participant laboratories. For type 1 samples, failure to report the specific pathogen or reporting an additional organism as a pathogen should [illegible] [illegible] responses divided by the number of organisms present plus the number of incorrect organisms reported will be multiplied by 100 to establish a score for each sample in each survey. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be 1/(1+1) x 100 = 50%. Sample scores are averaged to determine the survey score. Laboratories are expected to perform the isolation and identification process to the same extent they perform it with patient specimens. A laboratory's level of service will be used to determine the appropriateness of their response.

For antimicrobial susceptibility testing, laboratories should report those antimicrobial agents considered appropriate for the causative organism and infection site. Determination of which antimicrobial agents are appropriate should be based on a consensus document such as an National Committee on Clinical Laboratory Standards (NCCLS) publication. Grading should be based on the number of correct responses divided by the number of appropriate drugs tested. A laboratory must indicate which antibiotics are include in its test panel and will be evaluated only for those antibiotics for which service is offered.

A laboratory's survey score for bacteriology will be either the survey score for organism identification or, if the laboratory also performs antimicrobial susceptibility testing, the score determined by dividing the total number of possible organisms a laboratory should have identified plus the number of correct antimicrobial agent responses by the number of correctly identified organisms plus the number of additional organisms reported plus the number of appropriate antimicrobial agents tested. For example, if a survey contained 3 reportable organisms and a laboratory reported all three correctly, but reported one additional organism, and made one error in antimicrobial susceptibility testing of three appropriate agents tested, its score for bacteriology would be - (3 + 2)/(3 + 1 + 3) x 100 = 71%.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Criteria for Acceptable Performance

For the three most recent testing events or surveys, a laboratory must maintain a **cumulative average score of 70%** of acceptable responses for the three events or surveys for any recognized reimbursement or licensure speciality. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

A. [illegible] Challenge

In mycobacteriology, three types of laboratories are recognized:

1. Those that perform acid-fast stains and refer cultures to another laboratory for identification.

2. Those that isolate and perform identification of *Mycobacterium tuberculosis*, but refer cultures other than *M. tuberculosis* to another laboratory for identification and/or perform antimycobacterial susceptibility tests on the organisms isolated.

3. Those that isolate and identify all mycobacteria to the extent required for correct clinical diagnosis and/or perform antimycobacterial susceptibility tests on the organisms isolated.

In the area of mycobacteriology, an approved program would provide a minimum of two samples per quarter. Approved program providers will be required to furnish a description of samples that they plan to include in their program during each calendar year.

B. Evaluation of Performance

Responses will be evaluated on the basis of the accuracy of the response. Reportable organisms should be determined by the program provider. The correct response for each sample is determined by an 80% or better consensus among at least 10 referee or all participating laboratories. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality. Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses divided by the number of organisms present plus the number of incorrect organisms reported will be multiplied by 100 to establish a score for each sample in each survey. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be 1/(1+1) x 100 = 50%. Sample scores are averaged to determine the survey score. Laboratories are expected to perform the isolation and identification process to the same extent they perform it with patient specimens. A laboratory's level of service will be used to determine the appropriateness of their response.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

For the three [illegible] surveys, a laboratory must maintain a cumulative average survey score of 70%. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

Mycology

A. Program Content and Frequency of Challenge

In mycology, three types of laboratories are recognized that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

1. Those that perform direct examination and culture, recognizing the type of organism that is present and referring isolates to another laboratory for identification.

2. Those that isolate and perform identification to the genus and, in some cases, the species level or to the extent required to differentiate recognized pathogens from others.

3. Those that isolate and identify organisms to the extent required for correct clinical diagnosis.

In the area of mycology, an approved program would provide a minimum of two samples per quarter. An annual program must include representatives of five major groups of organisms: (1) yeast or yeast-like fungi; (2) dimorphic fungi; (3) dematiaceous fungi; (4) dermatophytes; and (5) saprophytes, including opportunistic fungi. Approved program providers will be required to furnish a list of organisms that will be included in their annual program during each calendar year. Some of the organisms representative of the five major groups will be varied from year to year. At least 50% of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens and organisms commonly occurring in patient specimens should be included periodically in the program.

As an example, the types of organisms that might be included in an approved program over time are listed below:

Example Program

Organism

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenchii
Exophiala jeanselmei
Fonsecaea pedrosoi

Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis
Zygomycetes sp.

B. Evaluation of Performance

Responses will be evaluated on the basis of the accuracy of the response. Reportable organisms should be determined by the program provider. Usually, the correct response for each sample is determined by an 80% or better consensus among at least 10 referee or all participating laboratories. A referee laboratory is a laboratory that has had a record of accurate performance for at least a year in a specific test speciality or subspeciality. Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for these additional erroneous organisms reported. Therefore, the total number of correct responses divided by the number of organisms present plus the number of incorrect organisms reported will be multiplied by 100 to establish score for each sample in each survey. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be 1/(1+1) x 100 = 50%. Sample scores are averaged to determine the survey score. Laboratories are expected to perform the isolation and identification process to the same extent they perform it with patient specimens. A laboratory's level of service will be used to determine the appropriateness of their response.

If a proficiency testing program offers more than the minimum numbe of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Criteria for Acceptable Performance

For the three most recent testing events or surveys, a laboratory must maintain a cumulative average survey score of 70%. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

Parasitology

A. Program Content and Frequency of Challenge

In parasitology, three types of laboratories are recognized:

1. Those that are able to recognize the presence of parasites but usually refer them to another laboratory for identification.

2. [illegible]
   a correct clinical diagnosis [illegible]
   for identification.

3. Those that identify parasites to the extent required to establish
   a correct clinical diagnosis.

In the area of parasitology, an approved program would provide a minimum of two samples per quarter. An annual program must include parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens and organisms commonly occurring in patient specimens should be included periodically in the program. Approved program providers will be required to furnish a description of samples that they plan to include in their program during each calendar year. Samples should include both formalinized specimens and PVA (polyvinyl alcohol) fixed smears, as appropriate for a particular parasite and stage of the parasite. Samples should contain protozoa or helminths or a combination of parasites. Some samples should be devoid of parasites.

As an example, the types of organisms that might be included in an approved program over time are listed below:

Example Program

Organism

Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschlii
Chilomastix mesnili

Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Enterobius vermicularis
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

Evaluation

B. Evaluation of Performance

Responses will be evaluated on the basis of the accuracy of the response. Reportable organisms should be determined by the program provider. Usually, the correct response for each sample is determined by an 80% or better consensus among at least 10 referee or all participating laboratories. A referee laboratory is a laboratory specific test specialty or subspecialty. Since laboratories [illegible] incorrectly report the presence of organisms in addition [illegible] identified principal organism(s), the grading system must p[illegible] of deducting credit for these additional erroneous organisms [illegible] Therefore, the total number of correct responses divided by [illegible] organisms present plus the number of incorrect organisms re[illegible] multiplied by 100 to establish a score for each sample in e[illegible] For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be 1/(1+1) x 100 = 50%. Sample scores are averaged to determine the survey score. Laboratories are expected to perform the isolation and identification process to the same extent as they perform it with patient specimens. A laboratory's level of service will be used to determine the appropriateness of their response.

If a proficiency testing program offers more than the minimum number of challenges required by the uniform proficiency testing program, evaluations of performance should be based on the entire set of samples and not the minimum number.

C. Criteria for Acceptable Performance

For the three most recent testing events or surveys, a laboratory must maintain a **cumulative average survey score of 70%**. Failure to participate in a survey, except when patient specimen testing is also suspended, will result in a score of 0 for the survey.

6.0 PROCESS FOR IMPLEMENTATION AND FOR UPDATING THE PROFICIENCY TEST PROGRAM

The program outlined in this proposal becomes effective af[illegible] publishes a Notice of Proposed Rule Making (NPRM), conside[illegible] the rule as a result of the comment period, and publishes a final rule.

A plan to implement the final rule would include some or all of the following:

1) A meeting between proficiency testing program providers and HCFA to establish an implementation plan and startup date for programs operating under the rule.

2) Establishing an annual review process for approved proficiency testing programs and a protocol for submission and approval of new or partial proficiency testing programs.

3) Establishing responsibilities under the implementation plan for the annual review and approval of proficiency testing programs, for assuring that laboratories have enrolled in proficiency testing programs that cover the scope of services offered, for evaluation of laboratory performance data to establish the correct response for each challenge included in a proficiency testing program, for evaluation of laboratory performance to establish whether an individual laboratory has passed or failed,

failures.

4) Establishing a board of review to update the requirements [illegible] components of an approved proficiency testing program evaluation of laboratory performance.

5) Establishing a mechanism for publication of revisions to the Secretary's requirements for program providers and participating laboratories.

Summary of Comments Not Resulting in Change [illegible]
and
Task Force Responses to Comments

Section 2.0 SCOPE

Comment: The proposal does not cover the areas of virology, cytology, histology, urinalysis, hemoglobinopathy, newborn screening, cytogenetics, drugs of abuse, or oncofetal antigens.

Response: *The Task Force considered each of these areas for inclusion in the program. They were not included in this proposal, however, either because the error rate has been found in the CDC program to be extremely low (urinalysis), or because there were concerns about obtaining suitable sample materials, or because of the lack of a professional consensus about what should be evaluated or how performance should be assessed. Nonetheless, the Task Force does consider these areas to be clinically important and supports their inclusion in the national program in the future. [illegible] anticipated that the developmental work [illegible] and professional organizations will event[illegible] satisfactory samples and evaluation crite[illegible] proficiency testing in these problem areas.*

Section 5.1 Chemistry

A. Program Content and Frequency of Challenge

Comment: The program should provide challenges fo[illegible] antidepressants.

Response: *These analytes will be considered as add[illegible] program at a later date. In the meantime, [illegible] professional organizations are encouraged to include these tests as well as others not currently in the national program in their proficiency testing programs for educational, improvement, or State regulatory purposes.*

B. Evaluation of Analyte or Test Performance

Comment: Target assignment should ideally be made by using reference methods or reference laboratory data, or both.

Response: *The Task Force agrees with the concept that accuracy should be scientifically based. Reference or definitive methods or materials provide the best means to assure that evaluations of performance are consistent with this approach. Unfortunately, the concept is not workable at present because of the lack of suitable materials or methods for many of the analytes included in the program. We do insist on a single target value for each analyte for each sample unless a scientifically valid reason exists for separate target values, such as for direct ion selective electrode measurements for serum sodium.*

[illegible]

Comment: Rationale for the criteria for acceptable response is not discussed.

Response: *Ideally, the criteria for acceptable laboratory performance should be based on the clinical usefulness of the test results. There are, however, no generally agreed upon medical-usefulness criteria, and most evaluations of laboratory performance have been made on the basis of the state of the practice. Usually, these assessments have employed a statistical approach classifying acceptable performance in terms of the distance (number of standard deviations) a result is from the mean of responses.*

This approach assures that a fixed percentage of laboratories will be classified as unacceptable. In some instances, the width of statistically based limits has been unreasonably narrow, prompting the development of fixed distance from the target value as limits for results that would be considered acceptable. In the absence of medical criteria for acceptable performance, we have defined acceptable performance using fixed criteria (when they appeared to be appropriate) and statistical limits elsewhere.

Comment: The criteria established for acceptable performance are too liberal; should use 2 standard deviations rather than 3 standard deviations.

Response: *Several comments were received that support the continued use of a 2-standard-deviation limit to identify laboratories that are on the fringe of acceptable performance. Most of these comments came from groups who have had experience in using a 2-standard-deviation limit to identify laboratories in need of improvement. The purpose of the uniform program is not to educate or improve laboratory performance but to protect the public from laboratory results that are so much in error that they might adversely affect patient care. Therefore, the focus of this program is on laboratories who are consistently providing inaccurate or imprecise results, not on those that are providing an occasionally deviant result. The use of 3 standard deviations to identify laboratories requiring regulatory attention follows the usual internal quality control model for identifying serious problems with the quality of results.*

Section 5.2 Hematology

A. Program Content and Frequency of Challenge

Comment: Provision needs to be made for on-site proficiency testing surveys.

Response: *Previous CDC studies (Am J Public Health 1982;72:1364-1368) suggest that on-site surveys conducted by trained laboratory surveyors can be very effective in identifying the source of analytical error in laboratories previously detected through mailed proficiency testing surveys. On-site proficiency testing has the* [illegible] of having [illegible] [illegible] such surveys may be justified if a laboratory's performance problems are serious. Mailed proficiency, however, remains the most effective method, both logistically and economically, to screen the performance capabilities of a large number of laboratories. Quarterly mailed assessment of performance has become the accepted standard in determining whether a laboratory is capable of delivering sustained acceptable performance. The CDC proposal would permit a mixture of mailed and onsite evaluations to be conducted but would require that some form of evaluation be conducted every quarter.

Section 5.4 Immunology (Serology) Note antigens (Microbiology)

A. Program Content and Frequency of Challenge

Comment: *The program should include cytomegalovirus antibodies,* Chlamydia trachomatis *antigen,* Cryptococcus neoformans *antigen, rotavirus antigen, toxoplasma antibody,* Legionella pneumophilia *antibodies, and* Mycoplasma pneumonia *antibodies.*

Response: Although tests for these antigens and antibodies are available, most laboratories do not offer the procedures and these tests were therefore not included in the program at this time.

D. Criteria for Acceptable Performance

Comment: *The grading criteria, permitting laboratories to fall outside 2 standard deviations, is too liberal.*

Response: The use of 3 standard deviations to identify laboratories requiring regulatory attention follows the usual internal quality control model for identifying serious problems with the quality o results.

Section 5.5 Microbiology

Bacteriology

A. Program Content and Frequency of Challenge

Comment: *More than two challenges per quarter should be required.*

Response: A consensus has not been reached on the number of samples that offers an appropriate challenge in microbiology. Program providers should be able to provide a program that evaluates laboratory performance for all six major groups of bacteria, while reducing the cost of the program under these conditions.

B. Evaluation of Performance

Comment: *Proficiency testing program providers should be able to decide overall pass/fail grade.*

[illegible] each challenge in their program. However, the boundaries for what constitutes acceptable performance are the responsibility of regulatory agencies, not the program provider. We will actively seek the opinions of professional societies, program providers, and other interested groups in establishing reasonable boundaries for acceptable laboratory performance.*

Mycology

A. Program Content and Frequency of Challenge

Comment: If the frequency of submission of specimens is quarterly, the results for mycology may not have been evaluated before the next set of specimens is submitted.

Response: *Although slow growing fungi may require two weeks to identify, program providers should be able to send participants the intended results for the survey before the next shipment of survey samples even if quarterly surveys are conducted.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date OCT 5 1987

From William L. Roper, M.D.
Administrator

Subject Memorandum of Understanding (MOU) Between HCFA and CDC

To James O. Mason, M.D.
Director
Centers for Disease Control

Thank you for forwarding the proposed MOU between CDC and HCFA concerning each organization's responsibilities for clinical labs covered by the Clinical Laboratories Improvement Act (CLIA '67) and the Medicare Program. After reviewing the attached agreement, I co-signed to indicate HCFA's concurrence.

Please express my appreciation to those members of your staff who contributed to updating the MOU. In addition, I look forward to continued cooperation between our organizations to successfully implement the terms of this document.

Attachment

CDC ID: D 40053
DATE: OCT 08 1987
Correspondence Unit, CD

MEMORANDUM OF UNDERSTANDING
Centers for Disease Control
and
Health Care Financing Administration

I. Background

The mission of the Centers for Disease Control (CDC), within the Public Health Service (PHS), is directed toward the prevention of unnecessary morbidity and premature mortality and the improvement of the quality of life. Disease surveillance, a cornerstone of public health activity, often depends on accurate and reliable information derived from laboratory tests.

CDC has for years worked to provide a focus for national efforts to assess the quality of laboratory performance and to promote the cost-effective delivery of laboratory services. Current efforts include the development of a comprehensive national laboratory data base to identify trends in laboratory performance and testing. The analysis of such data will likely lead to new opportunities for disease prevention by identifying problems at an early stage and assisting providers and users of laboratory tests in resolving those problems which impact on the quality and cost of health care delivery. For the past seven years, CDC has worked with the Health Care Financing Administration in support of its administrative responsibilities for clinical laboratories covered by the Clinical Laboratories Improvement Act (CLIA '67) and the Medicare Program.

The Health Care Financing Administration (HCFA) mission includes administering the nation's largest health care financing program. HCFA responsibilities include those of developing policies and procedures for surveying facilities for Medicare. In the laboratory area, HCFA is responsible for developing the administrative policies for certifying laboratories for Medicare as well as licensing laboratories under CLIA '67.

II. Purpose

The purpose of this agreement between CDC and HCFA is to establish a mechanism for focusing the Department of Health and Human Services resources on cost-effective regulatory tasks that have the greatest potential for improving laboratory performance and therefore health care delivery, while meeting regulatory responsibilities. This agreement is intended to replace the PHS-HCFA Interagency Agreement that was signed by the Secretary on March 17, 1979.

III. Responsibilities

A. Standards, procedures, and regulations

HCFA will be responsible for:

1. All statutory and regulatory provisions and their interpretation that relate to CLIA '67 and Medicare laboratory standards.
2. Developing regulations for the Secretary's approval and interpretation of regulatory requirements.
3. Replying to correspondence and inquiries pertaining to regulations and issuing manuals and instructions pertaining to those requirements for the guidance of HCFA's central and regional offices, Medicare State survey agency, and laboratory personnel.

CDC will be responsible for:

1. Initiating scientific studies to identify trends in laboratory performance and services that may result in a determination of a need for new or modified regulatory procedures or guidelines.
2. Providing or assisting HCFA in obtaining the technical and scientific expertise required to resolve issues raised by new technology, health care delivery modes, and changing laboratory service patterns.

B. Proficiency testing

HCFA will be responsible for:

1. Determining whether a proficiency testing program of a State or of an accrediting organization meets HHS requirements.
2. Assuring that laboratories participate in proficiency testing programs required by HHS to meet CLIA '67 and Medicare statutes and regulations.
3. Determining whether a laboratory is in compliance with proficiency testing performance requirements and initiation of adverse action proceedings as a result of unsatisfactory laboratory performance.
4. Promulgating and interpreting HHS requirements for proficiency testing programs.
5. Assuring that CDC personnel have access to Federally monitored laboratories to collect laboratory related information and that proficiency testing program providers supply CDC with complete and timely performance data.

CDC will be responsible for:

1. Developing uniform proficiency testing standards for CLIA '67 and Medicare.
2. Assisting HCFA with technical issues related to the determination of the equivalency of State and other accrediting organization proficiency testing programs to HHS standards.
3. Providing HCFA with an annual report concerning the equivalency of programs actually provided by approved proficiency testing programs.
4. Providing HCFA with proficiency testing performance data obtained from approved proficiency testing program providers on laboratories whose proficiency testing performance appears to be unsatisfactory.
5. Assisting HCFA in development of Federal Register notices with respect to proficiency testing.
6. Providing or recommending expert witnesses to HCFA for testimony at adverse action hearings.

C. Proficiency Examinations

CDC will be responsible for:

Providing a written examination, as required by Congress, to be used as an alternative means of qualifying clinical laboratory technologists under the CLIA '67 and Medicare programs.

HCFA will be responsible for:

Coordinating all other matters relating to interpretations of Section 1123 of the Social Security Act, including all proficency examination issues concerning health professionals other than clinical laboratory technologists.

D. Laboratory survey, approval, and licensure activities

HCFA will be responsible for:

1. Surveying clinical laboratories and applying the technical and scientific standards for purposes of the CLIA '67 and Medicare programs.
2. Approving and disapproving clinical laboratories for purposes of CLIA '67 and Medicare programs.

3. Conducting surveys of clinical laboratories to document and validate alleged significant deficiencies that, if present, would adversely affect the health and safety of patients.

4. Negotiating, approving, and administrating agreements with the Medicare State survey agencies for purposes of the CLIA '67 and Medicare programs.

5. Administrative review and hearings conducted in conjunction with adverse action proceedings for Clinical laboratories under CLIA '67 and Medicare.

6. Conducting reviews and evaluating the standards of third parties to determine whether they meet, or continue to meet, HHS requirements.

7. Determining whether clinical laboratories in a State or those accredited by a particular accrediting organization should be, or continue to be, exempt from the provisions of CLIA '67 or Medicare because the standards of the State or accrediting organization are equal to or more stringent than HHS standards.

E. Training and continuing education

HCFA will be responsible for:

Training laboratory surveyors of the Medicare State survey agencies with respect to technical and scientific standards, and administrative, procedural, and licensing requirements pertaining to CLIA '67 and Medicare programs.

CDC will be responsible for:

1. Providing HCFA with recommendations for training of laboratory personnel to remedy shortcomings identified during CDC training needs assessment activities.

2. Providing training of laboratory personnel to remedy training needs identified by State or local health laboratory administrators.

F. Research and development

HCFA will be responsible for:

Conducting studies pertaining to the coverage and reimbursement of clinical laboratory services, the survey, approval, and licensure of clinical laboratories, the appropriate administration and use of services.

CDC will be responsible for:

> Conducting studies pertaining to the technical and scientific aspects of health care delivery systems including quality control practices, data handling and reporting practices, evaluations of methodologies used in testing, trends in performance, and of variables identified as indicators or predictors of good and unsatisfactory performance of laboratories and health care delivery systems.

IV. Areas of Collaboration

CDC and HCFA have identified major areas of common interest including:

1. The maintenance of accurate and reliable laboratory testing to support health care delivery systems.
2. The coordination of efforts to obtain inputs from manufacturers, professional organizations, states, and other interested parties about health care issues.
3. The collection of comprehensive national laboratory data and the dissemination of information obtained from those data.
4. Assessments of trends in laboratory testing and in health care delivery aimed at identifying problems, finding ways to correct problems and to project future needs.

V. CDC-HCFA Meetings

In order to assure that these collaborations and responsibilities are pursued in a continuing and timely fashion, CDC and HCFA will meet on a regular basis as appropriate to the activities supported by this agreement, alternating meeting sites, and will share information, report on progress, and explore new areas of collaboration.

VI. Annual Summary

An annual summary of meetings and activities conducted under this agreement will be prepared and submitted to the Director, of CDC and to the Administrator of HCFA at the completion of each fiscal year.

James O. Mason

James O. Mason, M.D.
Assistant Surgeon General
Director, CDC

JUL 17 1987
Date

William L. Roper

William L. Roper, M.D.
Administrator, HCFA

OCT 5 1987
Date

[From the Wall Street Journal, Feb. 2, 1987]

FALSE NEGATIVE: MEDICAL LABS, TRUSTED AS LARGELY ERROR-FREE, ARE FAR FROM INFALLIBLE

HASTE, MISUSE OF EQUIPMENT, SPECIMEN MIX UPS AFFLICT EVEN BEST LABS AT TIMES

Regulation: Weak and spotty

(By Walt Bogdanich)

It was 4:30 a.m. when cancer finally choked the last breath of life from Janice Johnson. She was 34 and a mother of two, and she died never knowing why her disease had been so unforgiving. An autopsy report called her abrupt decline "quite unusual."

Later, an important cluse would be discovered: A hospital laboratory in Arlington, VA., had erroneously reported two successive Pap tests as noncancerous. Undetected, the cancer spread rapidly through Mrs. Johnson's body.

"The lab was never shut down or criticized," fumes Daniel Schultz, a Johnson family lawyer who in 1984 settled a wrongful-death claim against the hospital and several doctors for $600,000. He asks: "How many other Janice Johnsons are there?"

No one knows. For in many states, including Virginia, the clinical laboratories that test body fluids and tissues aren't licensed—and thus enjoy a freedom from regulatory scrutiny not accorded even to hairdressers. Some 20 years after Congress declared war on incompetent clinical labs, many researchers say that inaccurate and unreliable testing remains a serious health hazard as well as a waste of millions of dollars.

HARD DATA

In recent years, dazzling advances in computerized diagnostic testing have lent a comforting air of precision to the healing arts. Whether concerned about blood cholesterol, cancer, genetic flaws or diabetes. Americans spend an estimated $20 billion a year on clinical laboratory tests, often receiving impressively detailed printouts on the state of their health.

For the most part, such testing is a great boon to diagnosis and treatment. But along the way, patients have come to regard lab work as infallible—a dangerous assumption, critics say. "Every lab is producing some errors," warns Paul Fischer, an Augusta, GA., physician and authority in the field. "Human error is inherent in this process. . . . I don't think the public realizes that."

The problem affects not only fringe laboratories in inner cities but also prestigious hospitals, publicly traded laboratory companies and labs in doctors' offices, according to an analysis of thousands of pages of government reports, court records and previously unreleased test data. The recent surge of testing in doctors' offices is particularly troubling, critics say, because these small facilities are often entirely free of regulatory oversight.

FALSE STARTS

While sloppy lab work isn't as obviously dangerous as incompetent surgery—errors are often caught by a patient's physician—it can do great harm. An Ohio baby developed mental retardation after a lab failed to detect a genetic condition that required a special diet. An Arizona man died after a biopsy slide of his malignant thyroid tumor was misread by two different labs. A California couple's marriage broke up after one spouse was mistakenly diagnosed as having syphills.

Nor is health the only issue: A urinalysis that falsely tags someone as a drug abuser can sabotage the person's career.

Studies repeatedly have turned up substantial rates of laboratory error, as well as overworked or ill-trained technicians. But abuses are hard to prove, and accountability is scant. By the time an illness has progressed far enough to suggest earlier test error, the slide or specimen often has been discarded.

LITTLE REGULATION

Government hasn't come to grips with the problem. Regulation is so weak and uneven that labs barred from one state can simply do business in another. In some cases a federal agency has no choice but to reimburse certain labs for tests that it has found them incompetent to perform.

Concern over such problems prompted Congress to pass the Clinical Laboratories Improvement Act in 1967. Although the law covers only a fraction of the nation's labs—those conducting interstate business, legislators hoped it would be a model for state regulation.

However, only about half of the states have enacted laboratory regulation, and most of it is feeble. In 1979 the Senate Labor and Human Resources Committee concluded that the public "cannot have confidence in clinical laboratory testing, despite its critical relationship to good health."

Faulty tests can occur for many reasons: A machine loses its calibration: testing chemicals lose potency or get used improperly: human specimens are inadvertently switched. Even if a test is performed properly, it may be misinterpreted.

Over the years, the medical profession has developed standards to minimize such mishaps. Conscientious laboratories test chemicals and machine calibrations daily. They frequently test "master" specimens of known value to detect any glitches in equipment or procedures. But without oversight, adherence to these standards is left to the whim of the individual lab.

If, for example, Mrs. Johnson's Pap smears had been analyzed at a hospital in New York, where government standards are among the toughest, they would have been screened by workers who had faced proficiency tests and had to have 10% of their work checked by supervisors.

Such safeguards didn't exist at Northern Virginia doctors Hospital, whose lab supervisor conceded. In a deposition filed in Virginia state court, that Mrs. Johnson's two Pap tests were reported incorrectly one year apart by the same lab worker. The supervisor also said quality-control reviews weren't routine. The hospital declines to comment on Mrs. Johnson's death or her family's suit.

Some researchers worry that Pap-test "sweat shops" impair accuracy by overworking technicians. "I can't deny they are out there," says Thomas Bonfiglio, the president of the American Society of Cytology. "I think you'd have to be crazy not to be concerned."

The society recommends that, in the case of Pap tests, a full-time screener review no more than 10,000 to 12,000 slides a year. But about one-third of labs responding to a survey some years ago exceeded that workload, and records show that screeners at a lab just outside New York City currently have workloads three times greater. The Johnson family lawyer asserted that the worker who called Mrs. Johnson's Pap tests benign had an excessive workload.

Technicians must scan dozens of cells on each slide for abnormalities. "It's a very meticulous job," Dr. Bonfiglio says. "The error rate goes up as people get fatigued."

"SINK TESTING"

Boston researchers studied 10 women with cervical cancer who had had negative Pap tests in the preceding two years. A reexamination of their slides found that five had been misinterpreted and two slides were too poorly done to read; only three were clearly negative. Researchers at Harvard Medical School and the Boston Hospital for Women did the study.

An even worse situation occurred in the late 1970s at a lab that had won a contract to screen Pap smears for the Air Force. An Air Force pathologist charged that screeners at the lab, Automated Medical Services of Ohio Inc., were overworked. When government doctors reexamined slides it had processed, they found 5,949 "discrepancies" or "mistakes," says Patti Turner, a spokeswoman for the Air Force surgeon general. A search for women who had gotten false reports found most of them, though not all. The lab has closed, and its former officials couldn't be reached for comment.

Now and then labs have even reported on specimens without checking them at all—"sink testing," it is called. A Hempstead, N.Y. lab is alleged to have reported phony results for more than a year on blood tests for rheumatism, tuberculosis and various chronic infections. In September a state grand jury indicted the company, Reiss Health Laboratories Inc., on fraud-related charges. The lab, which has pleaded innocent, declines to comment.

Fraud, however, is much less pervasive than error. Nearly one in six labs tested recently by the Centers for Disease Control didn't properly identify several common strains of bacteria. One in seven failed to identify various fungal growths properly. "So many things can go wrong, even in the best labs," says Josephine Bartola, the director of Pennsylvania's laboratory improvement division.

DOCTOR'S-OFFICE LABS

Nearly half of outpatient lab tests now are done in physicians' offices, because of cheaper test equipment and changes in hospital economics. There are estimated to be between 40,000 and 100,000 such small labs, compared with 13,000 hospital and independent labs. The trend alarms many experts, because only 13 states even attempt to regulate labs in doctor's offices.

As a result, in all but a handful of states, their personnel needn't meet any training standards. Dr. Fischer, the authority on office laboratories, says that in as many as two-thirds of small doctor's-office labs, work is done by employees lacking formal lab training, including medical secretaries and receptionists.

When Idaho officials tested unregulated doctor's-office labs in the 1970s, fully half of them submitted erroneous or unacceptable results on a simple pregnancy test. "You'd get the same results throwing a coin in the air," Dr. Fischer remarks. (Their performances improved after they were instructed in the need for quality control and proficiency testing.)

Physicians with labs in their offices generally contend the new equipment is accurate and makes for faster diagnosis and better treatment. But David Yates, a pathologist in the Nashville, Tenn., area, says that "doctors don't realize how difficult it is to consistently generate accurate test data. People think it's a computerized situation where you always get a 100% accurate result: that's simply not true."

TWO STUDIES

Michael Kenney, a health-policy analyst, studied California clinical labs for the CDC in 1985 and found "a systematic pattern" of poorer accuracy by unregulated labs than by government-regulated ones. Another study, by Robert Grayson in 1984, reached a similar conclusion.

Even where office labs are regulated, the monitoring is usually superficial. California requires doctor's-office labs to submit proficiency test scores—but doesn't review them. "We aren't advertising that," confides Ronald Harkey, of the state lab division. He says his office lacks the computers needed for the task.

Pennsylvania, which does review proficiency tests, recently found that nearly half of the doctors sampled had erred in analyzing a test for bacteria. The state has some of the nation's toughest rules for doctor's-office labs, but its officials say they have never disciplined a doctor for faulty testing.

Ms. Bartola, the director of the state's laboratory improvement division, says her office will order a lab to stop offering a procedure, if it fails four consecutive proficiency tests. She says this has never occurred, so no stop orders have ever been issued. However, state records show multiple instances of doctor's-office labs failing four or more straight tests. For example, the lab of a doctor in Johnstown, Pa., Dinesh Mathur, failed 24 of 40 individual proficiency tests in 1984–85, including six in a row for blood glucose, yet the state didn't restrict his testing.

Asked about these records, Ms. Bartola says some failures may have escaped her attention because of a staff shortage. Besides, she adds, "We don't police them: we work with them until they come up to snuff." Ms. Bartola also says that many doctor's-office labs aren't licensed, as required by state law, and that she hadn't the staff to do much about it.

Dr. Mathur, who recently did pass a glucose proficiency test, says that his is a small lab doing few tests and that the state has never told him to stop. He also says he uses the best available equipment.

NEW YORK'S PROGRAM

The federal government is even more lenient. To get Medicare reimburements, commercial or hospital labs must submit to proficiency testing and inspections. Not so doctors, if they confine their testing to their own patients.

New York state, employing about 170 medical doctors and Ph.D.s, runs probably the nation's most stringent program of laboratory proficiency testing. Yet it doesn't oversee those in doctor's offices.

As for the labs New York does oversee—independent ones and those in hospitals—when the state last February tested their ability to measure 18 parts of a standard blood-chemistry analysis, 11% of the results were either unacceptable or only marginally acceptable.

New York, has issued more than 150 orders since July 1984 barring labs from testing in areas where they have failed to show proficiency. Many prominent labs, some with international reputations, have felt its regulatory sting, including the cytogenetics laboratory at Thomas Jefferson University Hospital in Philadelphia. That major referral center twice failed to pass New York's cytogenetics proficiency test in 1985, committing "major errors," according to Ann Willey, a scientist who heads New York's Laboratory of Human Genetics. Although barred from testing New York residents, it can continue to process specimens from other states.

Laird Jackson, the director of Thomas Jefferson's lab, says New York's proficiency tests were flawed. Besides, he adds, cytogenetics testing is subjective, akin to "judging ice skaters." Dr. Jackson says his lab has passed a proficiency test conducted by a major testing service outside New York.

A COMMERCIAL LAB

Another lab that has sometimes failed New York tests is the nation's largest publicly traded company exclusively engaged in testing human specimens, International Clinical Laboratories Inc. The Nashville based company's clients include 40 hospitals with 8,700 beds. In a recent two-year period, ICL's major referral lab failed New York state's proficiency tests for toxicology, which detects drugs subject to abuse, and mycology, which identifies molds sometimes associated with severe infections. Paul Ottaviano, an executive of ICL., says it passed proficiency tests administered by others, as well as government inspections, and has since passed New York's tests.

What are the consequences of laboratory error for patients? A cytogenetics test (for genetic abnormalities) may lead a woman to terminate a pregnancy. "If that diagnosis was wrong, it's a wrongful death," Ms. Willey asserts.

Laboratory mistakes needn't be unusual to be devastating. Caroline Kekiak, of Columbus, Ohio, says she suffered through two unnecessary operations because she was erroneously reported to be pregnant. According to a suit she filed in Ohio state court, the following occurred: Ohio State University Hospitals in Columbus admitted Mrs. Kekiak with abdominal pain in January 1985 and a blood test determined that she was pregnant. When an ultrasound exam detected a pelvic mass, doctors, thinking she had a tubal pregnancy, performed emergency abdominal surgery. But instead of an embryo surgeons found a cyst, and they removed her right ovary.

Mrs. Kekiak's suit says that as a result of the surgery, she later developed an abscess on a Fallopian tube and required a second operation to remove it. Except for the erroneous pregnancy test, the suit asserts, the cyst would have been treated with medicine and "no surgery would ever have been performed."

The suit attributes the faulty pregnancy test to a mix-up of specimens. A spokesman for the hospital declines to comment.

MEDICARE LOOPHOLE

The federal government tries to reduce errors by inspecting labs. But it is hampered by a surreal tangle of contradictory regulations.

Sharon Harris, of the federal Health Care Financing Administration (HCFA), says that if "people's lives are in danger," her agency can revoke a lab's Medicare certification. But the effect is merely to halt reimbursements for tests on Medicare patients; the lab can continue testing other patients.

St. Clair Medical Laboratory in Belleville, Ill., for instance, remains open seven months after federal regulators called it a health hazard and removed its Medicare certification. (An attorney for the lab says it has never been a health hazard and notes that it has remained licensed by the state.)

Another inconsistency: In 1985, after St. Ansgar Hospital Laboratory in Moorhead, Minn., failed proficiency tests, the HCFA barred it from doing a kidney-function test on specimens sent across state lines. Ms. Harris says such a stop-test order indicates patient safety is at stake. But because failing to demonstrate competence on a single procedure isn't deemed serious enough under Medicare rules to warrant regulatory action, the HCFA can't stop St. Ansgar from performing that test on Medicare patients, nor can it stop reimbursing for the test.

St. Ansgar says the lab has passed Minnesota proficiency tests. It won't comment specifically on the federal agency's action.

Since January 1985, the HCFA has issued more than 90 orders prohibiting labs from doing certain tests on interstate specimens, according to records obtained under the federal Freedom of Information Act. Most of these labs participate in the Medicare programs, so many of them continue to get federal reimbursement for the prohibited tests.

"It does seem very inconsistent," says the federal agency's Ms. Harris. "I'll admit it's a problem."

TRADE GROUPS

The government has also drawn fire for ceding regulatory oversight to private medical groups that, critics say, are lax in policing laboratories. For example, it essentially exempts from Medicare regulation labs in more than 5,000 hospitals accredited by the Joint Commission on Accreditation of Hospitals, a trade group. California's chief of laboratory field services Roderick Hamblin, says the commission "doesn't always adequately identify deficiencies in performance or . . . get them corrected." A Joint Commission official calls that notion "ridiculous."

Many states accept Joint Commission inspections in lieu of their own, but not New York. When a commission team inspected the Moses Lundington Hospital in Ticonderoga, N.Y., on Aug. 30, 1985, it reported nine laboratory deficiencies; New York state inspectors who checked the lab a few months later found 38. The Joint Commission won't comment on the case but says different inspections may emphasize different aspects of labs. Margaret Warden, the hospital's administrator, says hers is a small rural facility that is "doing the very best we can"

Under current rules, if the Joint Commission wants to decertify a lab, it must remove the accreditation of the entire hospital. The commission hasn't revoked any accreditation solely because of lab performance in recent years. "We . . . don't see ourselves at all in a policeman's role," says Jack Coale, a Joint Commission spokesman.

This view is shared by the College of American Pathologists, which runs its own accreditation and proficiency-test program for labs. It has revoked the accreditation of just one of 3,800 labs since January 1985.

"The whole basis our program is education and laboratory improvement," says John Duckworth, a doctor who heads its accreditation commission. "Ours is not a regulatory program."

Since Congress passed its laboratory legislation 20 years ago, it has tried five times to strengthen the law. Each effort, opposed by organized medicine, failed. The HCFA would like to see states take a bigger role, but organized medicine makes its presence felt in state capitals, too. Its influence, along with the issue of costs (New York spends $2.2 million a year to oversee labs) has helped keep state laws limp.

OFFICE MACHINES

Many doctors argue that technological advances make regulation less important. They note, for example, that new glucose-monitoring machines are so simple to operate that diabetics use them at home.

But the machines don't inspire universal confidence. In the past two years, the Food and Drug Administration has received about 1,200 reports of problems associated with glucose monitors. In one such report, a hospital complained that its machine wasn't working right; when the manufacturer checked, it found employees had apparently been using the device even though it was broken, dirty and held together with a rubber band. In dozens of other cases, technicians were found to be using the machines improperly. An FDA task force is investigating.

Growing evidence of testing abuses, along with fear of malpractice litigation, has begun to stir concern in some quarters of the medical establishment. Since late 1985, the Journal of the American Medical Association has been running a series of articles on office testing. Physicians, the authors have written, "are unfamiliar with . . . the subtleties of testing, the idosyncratic personalities of 'foolproof' electronic equipment, or even the basic concepts of quality control."

Observes Walter Johnson, the director of the cytogenetics lab at Case Western Reserve University in Cleveland: "Most of us would prefer that regulation be on a voluntary basis. But frankly, voluntary systems don't work worth a damn in the long run."

[From the Wall Street Journal, Feb. 2, 1988]

LABS OFFERING WORKPLACE DRUG SCREENS IN NEW YORK HAVE HIGHER ERROR RATE

(By Walt Bogdanich)

Last August, New York state laboratory regulators tried a little experiment. With many firms rushing to sell drug-testing services for the workplace, the state wanted to know how they would do on state proficiency tests.

Lab officials were surprised and worried by what they found. Testing errors were made by 66% of the labs offering drug screening in the workplace—an error rate three times greater than recorded by labs that don't offer the service.

Researchers were intrigued by another finding about labs that sell employee drug-screening services: Most of their mistakes were false negatives—failures to detect drug traces they should have found—rather than the opposite error. "What this is telling me is that if there is any question at all, the laboratories are likely to say it is negative," says Richard Jenny, a research scientist with New York's lab division. "You are defeating the whole purpose of the drug testing program."

Mr. Jenny suspects that labs are reacting to legitimate public concerns that tests might mistakenly identify some employees as drug users, causing great harm to their careers. But, he cautions, if a drug abuser has a job that affects others, such as flying an airplane, "then I would certainly want a correct test result."

The results don't mean that labs have eliminated the problem of finding drug traces where none exist. Last spring, the College of American Pathologists checked the drug-detection skill of nearly 500 labs nationwide and found that in 5% of the cases—a total of 358 instances—the labs reported finding drugs that weren't present. About half the errors involved drugs subject to abuse.

Thorne Butler, a physician who helped to administer the tests, says they suggest that some labs are violating a prime principle of drug screening, the need to confirm all positive findings by alternative methods. False positives can result from taking certain over-the-counter medications or even from eating a poppy-seed roll, researchers say.

The problems don't afflict only small or obscure labs. New York state officials say a major SmithKline Beckman Corp. lab in suburban St. Louis failed repeatedly to identify all drugs present in test samples. A SmithKline spokesman says the lab has changed its testing procedure and has passed the New York test.

With big, conscientious labs making testing errors, regulators fear that small, inexperienced ones in nonregulating states may be doing much worse. Referring to such small labs, William O'Neil, a past president of the American Clinical Laboratory Association, says, "I think any company that would buy tests from a laboratory like that is crazy, yet it's done."

[From the Wall Street Journal, Feb. 3, 1987]

RISK FACTOR: INACCURACY IN TESTING CHOLESTEROL HAMPERS WAR ON HEART DISEASE

SOME DIAGNOSES ARE SKEWED BY GLITCHES SUCH AS USE OF ILL-CALIBRATED LAB GEAR

Missing the mark by 100 percent

(By Walt Bogdanich)

In September 1985, a research group called the American Health Foundation hit upon a way to publicize the link between high blood cholesterol and America's No. 1 killer, heart disease. It co-sponsored a five-day "health fair" in New York offering free cholesterol checks.

Organizers, who expected maybe 2,000 or 3,000 visitors, were stunned by what happened. Nearly 30,000 people showed up, some waiting in line for three hours. The sponsors hired a plane to rush in extra lab equipment, but still had to turn away half the crowd.

Americans in large numbers are finally beginning to comprehend what heart researchers have been telling them for years: High blood cholesterol can kill. But while heart researchers publicly urge cholesterol tests, they privately worry that their battle against heart disease is being undermined by inaccurate or misleading laboratory tests.

WAY OFF

When a physicians' group in 1985 asked 5,000 of the nation's top laboratories to run cholesterol tests on identical samples, nearly half produced results that a leading expert calls "unacceptable." Some labs weren't even close.

In the test, the College of American Pathologists sent each lab a sample with a known cholesterol value of 262.6 milligrams per deciliter. The laboratories came back with reports ranging from 101 to 524.

Cholesterol, a substance needed for such functions as making cell walls, is produced in adequate quantities by the liver. But many people have an excess of it circulating in their bloodstream, usually traceable in part to a diet high in animal fats. It now is clear that too much cholesterol increases arterial deposits that can restrict blood flow to the heart. Each year 550,000 Americans die from coronary heart disease, more than from all forms of cancer combined.

High cholesterol is of course only one heart-disease risk factor, along with such things as smoking, high blood pressure and family history. Until a few yers ago, there was much controversy over what danger a patient faced if cholesterol was high. But the National Institutes of Health has reached a consensus that 50% of adult Americans have levels high enough to worsen their risk of heart disease, and many leading cholesterol researchers believe the figure is even higher. For those with elevated levels, the NIH calculated each 1% reduction in cholesterol lowers heart-disease risk 2%.

A COMMON TEST

About 100 million blood cholesterol tests were performed in the U.S. last year, at a cost to patients and insurers of between $1 billion and $1.5 billion. In the future, the test is expected to be done even more frequently. Already it is among the most common clinical laboratory procedures.

Without accuracy in these tests, however, treatment is problematic. "We will never have good cholesterol therapy unless the doctors know that they can depend on the laboratories," says Gerald Cooper, a physician at the U.S. Centers for Disease Control.

Patients who falsely test low may forgo diet or drug regimens that their doctors otherwise would prescribe. Patients who falsely test high may face the unpleasant side effects of cholesterol-lowering drugs, to say nothing of an unnecessary cost of up to $125 a month. "That's a car payment for many people," notes one researcher.

WHAT CAN HAPPEN

Why do some tests mislead: Laboratory experts say some companies scrambling for a share of the growing market for cholesterol-measuring devices are selling machines they haven't taken the time to calibrate precisely. In addition, the people doing the tests may be equipment incorrectly, or they may buy chemical supplies not meant for their model of analyzer. And physicians may not properly interpret test results, in part because some lab reports include outdated information on what is "normal."

This reporter sent samples of his blood, all drawn at once, to five randomly selected New York City laboratories. Each reported a different cholesterol level. One gave a reading of 220, which, by NIH guidelines for his age group, falls on the borderline average and moderate risk. Another lab reported 245, putting the reporter in a high-risk category. The variation could mean the difference between modest dietary changes and expensive drug treatment.

This informal experiment involved just a few laboratories, but the one done by the Colleage of American Pathologists tested 5,000, many of them hospital labs. The egregious misses—50% too low or 100% too high—weren't common, but almost half of the labs did miss the result by more than 5%, says Herbert Natto, a clinical biochemist at the Cleveland Clinic and a leading authority on cholesterol testing. He says such a deviation is unacceptable.

Mr. Natto, who heads an HIH panel investigating testing procedures, adds that "many commercial and private labs—even medical centers—have as much as a 20% margin of error."

The pathologists' group won't release names of labs participating in its test, but records of a regular New York state test of laboratory proficiency illustrate Mr. Natto's point. One lab owned by Roche Biomedical Laboratories Inc. was 24% too low on a 1985 test sample. But another lab owned by the same company was 42% too high, state records show. A spokesman for Roche, a unit of Swiss-based Hoffmann-La Roche Inc., says the two labs have performed very well in subsequent proficiency tests and have never run afoul of government regulators.

In assessing a patient's risk, many doctors want to know what portion of the cholesterol is packaged as LDL (low-density lipoprotein) and what portion as HDL (high-density lipoprotein). LDL is the danerous type that can clog arteries. HDL is essentially used cholesterol on its way out of the body, and a higher level of it is thought to be a good sign. But measuring these fractions requires an extra laboratory procedure, and researchers say such testing is even more subject to error.

CHEMICAL CHANGE

In tests for overall cholesterol level, some of the skewed reports are believed to result when a lab uses inappropriate chemical "reagents." During testing, reagents are added to the specimen and produce a by product, the color of which is measured by the analyzing machine. In their marketing, manufacturers occasionally discount the machines themselves, intending to make up the lower price through sales of regents. But Robert Rej, a biochemist who heads New York state's climical chemistry laboratory, says labs sometimes cut costs by buying less-expensive reagents not designed for their model of machine.

Labs often confuse doctors by noting in their test reports whether the cholesterol level is "normal," or within an acceptable reference range. These "normal" ranges differ widely and can run as high as 330—far above what cholesterol experts agree is safe. "No wonder the physician does not get excited and intervene" in many cases, Mr. Natto says.

Labs commonly use the reference range supplied by the maker of their testing equipment. However, many manfacturers don't base the range on established links between cholesterol levels and coronary-artery disease. Instead, they may simply set up a statistical curve after testing new equipment on employees or others who appear healthy.

Robert Galen, chairman of the Cleveland Clinic's biochemistry department, believes "normal" ranges for cholesterol shouldn't be used at all. With total blood cholesterol, in most cases more is worse, he says, "so the notion of normal is not operative."

Some testing problems may result when equipment performs well in factory tests but poorly in the field, researchers say. "The laboratories are very dependent on what comes out of the factory and whether it will maintain its performance later," says Basil Rifkind, a physician at the National Heart, Lung and Blood Institute.

OFFICE TESTING

Of particular concern are the newer, cheaper models, called "black boxes" by some in the laboratory business. Aimed at physicians' offices, these analyzers can cost as little as $5,000. (More sophisticated machines cost well over $100,000.) "You are going to see these little black boxes coming out of the woodwork from all over because they [makers] see a market, "says one researcher.

Many in the medical field welcome the low-priced devices. They say the analyzers are accurate and are so quick that patients can receive these results in minutes instead of days. They can also be used at health fairs, like the one in New York, for large-scale screening. A physician who has his own cholesterol analyzer can bill for the test instead of passing the work on to a laboratory.

But quality varies widely among these analyzers as well as others, test data show, "The problem here has to do with the science of laboratory medicine and pathology. There is more than one way to measure cholesterol," says the Cleveland Clinc's Dr. Galen. More than 30 different machines are currenty sold, using somewhat different chemical processes.

After the College of American Pathologists proficiency test, researchers studied the performance of different machines used in the test. Some scored well, but others did not.

The Beckman Astra 8 analyzer, for example, had an average margin of error of 27%. A spokeman for the machine's manufacturer, Philadelphia-based SmithKline Beckman Corp., says that the test sample was flawed, and that if any problem existed, it has since been corrected.

SETTING THE DIAL

A major cause of inaccuracy, scientists say, is the sale of poorly calibrated instruments. George Bowers, a member of the NIH panel investigating cholesterol testing, notes that making properly calibrated equipment is time-consuming, and he says it is possible some manufacturers truncate the process for fear of losing market share. "If physicians don't demand accuracy—and by and large they don't—then manufacturers lack the incentive," Dr. Bowers says.

Manufacturers needing help with calibration can get it from the CDC and the National Bureau of Standards. Says the CDC's Dr. Cooper: "We offer industry a standardization program. We have invited them and done everything in our power. But, to put it bluntly, we have had a limited response."

Nathan Gochman, a manager of clinical instruments for a unit of SmithKline, replies that manufacturers can't count on this assistance because it isn't always available. He concedes, however, a need for manufacturers to agree on a "standardized protocol" to ensure that different machines produce the same results.

Richard Flaherty, vice president of the Health Industry Manufacturers Association says he knows nothing about manufacturers refusing calibration assistance. He says his membership recognizes the need to standardize test results and is working with scientific community to do so.

The NIH panel investigating cholesterol testing says its goal is to help manufacturers and labs to get to the point where the margin of error is no more than 5%. It hopes ultimately to reduce the rate to 3% or less.

Not that such accuracy would be the end of the cholesterol battle. About two years ago, the American Health Foundation, through cholesterol screening, identified individuals at high risk of heart disease. Six months later, those who had subsequently seen a physician were asked what happened. In most cases, a foundation spokeswoman says, "their doctor told them not to worry about it."

[From the Wall Street Journal, Nov. 2, 1987]

LAX LABORATORIES: THE PAP TEST MISSES MUCH CERVICAL CANCER THROUGH LABS' ERRORS

CUT-RATE "PAP MILLS" PROCESS SLIDES USING SCREENERS WITH INCENTIVES TO RUSH

Misplaced sense of security?

(By Walt Bogdanich)

The Pap smear. Over the past three decades, it has sharply reduced deaths from cervical cancer. Women and physicians trust it, so much that the Pap smear has become one of the most common laboratory tests in America.

It is also one of the most inaccurate. No one knows how many women die because a lab botches the analysis or a doctor takes an inadequate specimen. The test, as it is being done today, fails to detect roughly one in every four cases of cancer or precursor cell abnormalities.

Linda MacNeil was one victim. A Florida store manager, Mrs. MacNeil suspected cervical cancer after experiencing bleeding, but a Pap-test report reassured her. Four months later, another test found cancer. Mrs. MacNeil died at age 36.

Cindy Gray's Pap smear wasn't analyzed in a laboratory at all, but in the home of a lab employee, in violation of a federal regulation. There was no supervision and no pathologist to consult. Although the test reported no malignancy, the North Carolina mother of three was found soon after to have cervical cancer. She died at 34.

Barbara Arbuckle, of Seattle, was luckier: She is still alive. The 25-year-old woman received negative Pap-test reports, from two different labs, in the months before finding out she had invasive cervical cancer.

INCENTIVES TO HURRY

To find out why the Pap test falls so short of its promise, this newspaper visited labs, inspected records and interviewed doctors, lab workers and government officials. What emerges is a picture of a Pap-screening industry kept afloat by overworked, undersupervised, poorly paid technicians. It is an industry that often ignores what few laws exist to protect women from slipshod testing.

Across the nation, high-volume, cut-rate laboratories, sometimes called Pap factories of Pap mills, allow technicians to analyze up to four times as many specimens per year as medical experts recommend for accuracy. Many of them pay screeners on a piecework basis that encourages them to rush the analysis.

Some technicians work two or more jobs, earning as little as 45 cents to do the key analysis on a test that may cost the patient $35. In some cases, they say they are penalized if they resist the pressure to screen more slides in a day.

WORK AT HOME

"I think women whould be horrified to learn what's happening out there," says Dwight Golann, former chief of consumer protection for the Massachusetts attorney general's office.

Women and their doctors might be surprised to learn that labs often let employees take slides home to screen. "That borders on fraud," says Myron R. Melamed, a physician at Memorial Sloan-Kettering Cancer Center in New York.

Pap mills prosper by underbidding competing labs, charging as little as $1.50 per test. They are sought out by some gynecologists, who profit by marking up lab fees on patient bills.

COST PRESSURE

But their bargain rates also appeal to budget-conscious administrators of group health plans and government-funded clinics. Thus, at a time when pressures are great to restrain medical expenses, problems with Pap-testing accuracy exemplify the possible trade-off in quality of care.

The consequences of faulty testing pose disturbing questions for the medical establishment. An estimated 60,000 women this year are expected to develop cancer of the cervix. If caught early, the disease is nearly always curable. Yet it kills about 7,000 American women a year.

"It is time for the medical community to acknowledge the failures of cervical cancer screening in the U.S.," says Robert Hasselbrack, a pathologist who runs a clinical laboratory in Seattle. Another physician, San Francisco pathologist Eileen King complains: "Women have been told for many years that a Pap smear will tell them when they have cancer and when they don't. That is a big falsity."

Heightening the urgency is the fact that some doctors now believe cervical cancer develops faster than previously believed. Also, they see it turning up in more young women.

Citing an "alarming number" of cervical-cancer cases in women with recent negative Pap smears, the American College of Obstetricians and Gynecologists has criticized the American Cancer Society for advising women that they need a Pap test only every three years after two consecutive negative annual tests.

"Nothing merits total faith, but nobody can doubt its [the Pap test's] value," says Robert Hutter, a physician who is a past president of the society. Still, the society is considering recommending that women take the test more frequently.

Leading cancer specialists say about half the Pap-test failures result because physicians take inadequate cell samples. But efforts to better educate doctors in taking specimens have been "spectacularly unsuccessful," says the obstetrician and gynecologist association.

Labs could help by rejecting inadequate slides sent to them. But "even good labs" are reluctant to do so, for fear of losing business, says Dr. S.B. Gusberg, another past president of the American Cancer Society.

WALLPAPER CHALLENGE

The Pap test is named for George Papanicolaou, who developed it in the 1920s. To prepare a specimen for the test, a doctor smears cells from the female genital tract onto a glass slide, in some cases two slides. Most aren't analyzed by a doctor but by a cytotechnologist, who ordinarily is a college graduate with a year of special training. Unlike some kinds of medical tests, Pap smears aren't checked by chemical or mechanical means but depend on human visual examination of the specimen.

A slide may contain hundreds of individual cells, each of which should be studied under a microscope. It is tedious work and, if done properly, time-consuming. Louise Newton, an Albany, N.Y., "cytotech," likens the job to examining wall after wall of flowered wallpaper.

"Imagine trying to look at every flower and see how buggy you get," she says. "Tired eyes make mistakes."

Accordingly, the American Society of Cytology recommends that no full-time cytotech examine slides from more than 12,000 patients a year. A 1980 conference of cancer specialists convened by the National Cancer Institute also supported this limit. But it is flagrantly ignored.

WORKLOAD CONTROVERSY

An analysis by this newspaper of government data found that more than half of the Pap smears sent to New York state-regulated labs are screened in places where technicians exceed the recommended workload. Kyto Diagnostics Inc. of New City, N.Y., a large private lab run by a prominent cytopathologist, Ralph Richart, reported average workloads of 35,000 cases per screener last year—nearly three time what the cytology society thinks is safe. Most of his screeners aren't even full-timers.

Dr. Richart and other critics of work-load limits say some cytotechs can accurately screen more than others. They argue that those who make excessive errors will be caught if a lab randomly rescreens at least 10% of negative slides.

Other medical experts disagree. Because only a small percentage of slides are likely to be positive, they say, and because everyone makes some errors, finding a problem employee might take years using a random 10% rescreen. "It's a seriously flawed quality-control technique," concludes Robert R. Rickert, vice chairman of lab accreditation for the College of American Pathologists.

Even as Pap-smear volume is rising, the number of qualified screeners is shrinking. Fewer people are choosing the field, and many are leaving it for better pay. Nearly half the schools that train cytotechs have closed in recent years; hospitals no longer find them economic to run.

"It is approaching a crisis," says San Francisco's Dr. King, who is studying the problem on behalf of California pathologists. Nearly 50% of advertised positions for cytotechs in California remain unfilled, she has found. Paul Krieger, director of anatomic pathology for MetPath Inc., a laboratory unit of Corning Glass Works, says that if the American Cancer Society decides to recommend more frequent Pap testing, "I don't know how we or anyone else is going to handle it."

To cope with the labor squeeze and to lower their costs, labs are turning increasingly to piecework, promising cytotechs that the more slides they screen, the more they will earn. Nowhere else in laboratory medicine is this method of payment so prevalent. "It's very bad practice. It makes quality control difficult," says Dr. Melamed of Sloan-Kettering.

Some big commercial labs pay almost exclusively by piecework, avoiding many employee costs. Even labs with salaried cytotechs, such as MetPath, usually let them do extras on a piecework basis.

Karen Sanford, a cytotech in Stockton, Calif., left a high-pressure piecework lab in the Los Angeles area after learning from a patient's doctor that she had failed to catch some abnormalities. "It really freaks you out," she says. "What do you say? It happened to me twice. That's when I decided to get out of there."

Not everyone is so conscientious. A particularly dangerous, yet very common, practice among cytotechs is to piggyback Pap-smear screening jobs, doing the maximum allowed at one lab, then meeting another lab's quota later in the day.

MIDNIGHT OIL

"Over 50% of the people I know have two jobs. Some have three or four," says Jason Betterton, a cytotech in Sylmar, Calif. Ms. Sanford tells of a technician who screens at three labs, working from 1 a.m. until late the next afternoon.

Labs frequently let workers leave for the day as soon as they reach their quotas—another incentive to screen slides as rapidly as possible. Lon Barr, a cytotech in Poway, Calif., says that when he joined a San Diego Pap lab he was "astonished" to see workers screen 100 slides in 3½ hours, then leave. "It was inconceivable that someone could screen that fast," he says.

Dr. Hasselbrack, the Seattle lab owner, says that in Pap mills, screeners lose sight of the fact that "you are looking at somebody's life, and if you make a mistake, it may be all over."

Piecework pay scales also encourage overwork. At 50 cents a slide, one who stuck to the cytology society's workload limit would earn only $6,000 a year.

LITTLE REGULATION

Only one state, California, even attempts to prevent workload abuses. Its law states that "no cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases, or 50 two-slide gynecologic cases per day."

But labs often violate or skirt this law. Start with the biggest Pap lab in the country. Cancer Screening Services, of North Hollywood. Almost a million Pap cases were processed last year by this unit of American Cytogenetics Inc. (which a West Coast business magazine in 1985 dubbed California hottest stock).

Cancer Screening's full-time employees are required to do 100 slides a day, says Shahia B. Sadeghi, medical director. It has mostly one-slide cases. Reminded of the state's legal limit, Dr. Sadeghi says: "It's not really a law—they just suggest it. . . . They know, it's not possible." She adds, "Every year we have passed the [state] inspection."

At Central Diagnostic Laboratory in Tarzana, Calif., says former employee Betty Jo Thompson, "there was no such thing as you couldn't do your 100 cases." Moreover, screeners were expected to do extras at $1 a slide, she says. California law lets workers analyze an unlimited number of Pap smears a day if they "volunteer," but Mrs. Thompson says that when she resisted doing extras, the lab cut her salary.

Cyrus Milani, a Central Diagnostic medical director, says workers are sometimes required to do 100 cases daily. He declines to be interviewed further, except to state that the lab does quality work. Another company official denies that the lab violates any laws.

At Yosemite Pathology in Modesto, "100 slides is what we consider the minimum," says spokesman Robert Colletti. He doesn't feel he is violating the law because "everybody interprets it differently."

FEW PROFICIENCY TESTS

Stephanie Harner, past president of the California Association of Cytotechnologists, says she has complained repeatedly to state health officials about pressures on cytotechs to exceed quotas, but "got mostly a non-response." Kenneth Kizer, director of California's health department, denies that his office has received complaints from cytotechs. He promises to investigate.

The federal government doesn't care about workload or piecework issues. It does prohibit labs under its jurisdiction from letting "kitchen cytologists" analyze Pap tests at home, but many do so anyhow. At the home, pathologists aren't available for consulation, and no one checks how carefully slides are examined. "Cytology is done in so many nooks and crannies—places we don't even know of," says Susan Yokota, a cytotech.

Cancer Screening Service, for example, if federally certified as an interstate lab, yet it concedes that workers in the past took slides home. The company says that happened only a few times and is no longer permitted. A Tulsa, Okla., laboratory permitted home screening of smears from government-financed clinics until a Journal reporter began inquiring about the practice.

The only equipment needed for Pap screening is a microscope. But as one lab worker points out. "It's not something to do after a day's work in between washing dishes, with kids screaming for attention."

Patients believe the government is watching over Pap testing, says Lawrence Bergner, a physician at the National Cancer Institute, "but it ain't so." The government sets some standards for interstate and Medicare-certified labs, but the Pap test is the only common lab procedure for which federally licensed labs needn't undergo periodic proficiency tests.

As for the states, only one, New York, requires screeners to pass such tests.

Doctors seeking quality work often turn to professional groups that evaluate and accredit labs. However, the largest group overseeing commercial labs, the College of American Pathologists, doesn't set any overall workload limit. The American Society of Cytology, which does, has certified only about 40 of the more than 1,000 labs analyzing Pap smears nationwide. Many of the largest labs have never sought accreditation.

With weak laws and scant professional oversight, there is little to protect women from the kinds of misfortunes suffered by Mrs. MacNeil, Mrs. Gray and Ms. Arbuckle. In all three instances, there Pap slides were misread, according to testimony in lawsuits filed in their state courts. Ms. Arbuckle's suit is pending; survivors of the other two women received large monetary settlements.

ELUSIVE SLIDES

It often is impossible, however, to determine what went wrong—whether the specimen was misread by the lab or whether, perhaps, it was poorly taken by the doctor. Pap slides are often kept only as long as the law requires. In states without laboratory laws—which is nearly half of them—a lab needn't keep slides at all unless it operates in interstate commerce or is Medicare-certified. In that case, it must keep them two years.

Patricia Ashton, a cytotech and consultant to a major national laboratory, says that her lab's lawyers instruct workers to "get rid of slides as soon as possible" to limit liability. "I don't think its medically ethical," she says.

Even if a suspect slide exists, retrieving it can be a problem. A now-defunct Boston laboratory called Elm Medical Lab, after having failed to detect a woman's cervical cancer, covered up the error by substituting a negative Pap slide for a positive one in her file, according to evidence presented by the Massachusetts attorney general in a state court. A jury last year found the lab had violated state consumer-protection laws; the case is on appeal.

Mr. Golann, who handled the state's case, also presented evidence that slides were improperly prepared at the lab; that one screener spent just seconds on each specimen; that slides were examined at home; and that the lab had failed to find the abnormal cells on 10 of the first 12 positive slides checked by investigators in a rescreening.

The dimensions of some abuses have been stunning. A Mansfield, Ohio, lab in the late 1970s was discovered to have sent out nearly 6,000 erroneous Pap-test reports. A world-wide alert located many, but not all, of the women affected. And this past September, health authorities in Britain issued an international alert for 911 women who had Pap smears misdiagnosed by a leading pathologist there.

PLANNED PARENTHOOD

Bad lab work is currently a paramount concern for Planned Parenthood Federation of America, which last year took 1.4 million Pap smears through affiliated offices and clinics. Early this year, Planned Parenthood warned affiliates of "a rapid rise in the number and cost of claims" due to laboratory errors, specifically Pap smears.

A few years ago, it tried to catch a lab it suspected of misreading Pap slides. Twice it sent the lab, which it won't name, slides from women known to have cervical cancer or its precursors, and twice the lab failed to report abnormalities. When Planned Parenthood tried to retrieve the specimens one set was said to be lost and the other came back smashed. It was as if "they beat them up with a hammer," recalls Louise Tyrer, a physician who is vice president for medical affairs.

With complaints about lab work pouring in, Planned Parenthood has begun trying to identify problem Pap labs. One lab that has come to its attention is International Cancer Screening Laboratories in San Antonio, Texas. Among the largest in the nation, ICSL processes about a half-million slides annually from 49 states. In 1985, it was banned from operating in New York after failing the state's proficiency test in cancer screening.

ICSL, operating out of a modern building on the outskirts of San Antonio, employs 42 screeners full or part time. It pays the part-timers 50 cents a slide and gives salaried employees 45 cents for each slide they screen after meeting the daily quota.

BIG PRODUCER

One screener is recorded as having analyzed 4,710 slides in June. That is a rate more than four times what the American Society of Cytology considers the maximum safe workload. Even if he worked all 30 days in June, the screener would have to have done 157 slides a day.

At such rates, "I wouldn't expect a cytotech to screen effectively or reliably," says George H. Anderson, a physician at the Cancer Control Agency of Vancouver, British Columbia, which has a highly regarded Pap screening program. Says Dr. Hutter of the American Cancer Society: "If such things are happening, then I would say that's terrible."

ICSL's president, Robert Boughton Jr., says that his lab's work "is the best humanly possible," and that he spends more money than other labs do on quality control. He also says the especially prolific screener's error rate is well within acceptable ranges.

But in a business where one mistake can have tragic consequences, the technican, who declined to be interviewed, last year made at least 93 errors—41 of them "major," lab records show. And those are just the ones uncovered in a routine rescreening of 18% to 20% of his negative slides. No one knows his actual error total.

Mr. Boughton attacks workload limits as the creation of physicians who "sit up in their ivory tower with a bottle of wine" and issue pronouncements. Lending authority to his attacks on workload limits is a Ph.D. degree he says he earned in biology from the University of Mexico in Monterrey "in 1981 or 1982." He is identified in state and federal regulatory records as having a doctorate.

The University of Mexico, however, doesn't have a branch in Monterrey. And no record of Mr. Boughton's Ph.D. could be found at two other universities in that city. Mr. Boughton declines to provide a copy of the diploma, saying, "I am telling you that I have it, and that it all I have to say."

Present and past screeners, who ask not to be identified, say that despite ICSL's huge volume, it's medical director works only part time. They also say that 10% or more of the slides sent to the lab are broken in transit. "You could easily miss an abnormality on the broken spot," says one ICSL cytotechnician.

Mr. Boughton says the breakage rate is "5% to 7% at the most." He says that while his medical director holds another job with a state mental hospital, she puts in nearly full-time hours at ICSL. He also makes no secret of the fact that he continues to operate in New York state, even though it banned his lab in 1985 after it failed the cancer-screening proficiency test. "Who's going to stop me?" he asks.

A spokesman for the state, Mary Anne Gardineer, says, "If we can verify that [ICSL] is accepting samples from New York state, we will stop them."

Amid growing criticism of laboratory work, the American Society for Cytotechnologists is pressing for tough government workload limits—even though they would reduce many screeners' pay. "Just as the public needs protection from fatigued truck drivers," the society says, "it needs protection against life-threatening mistakes in the laboratory by overburdened personnel."

Meanwhile, the society has begun a campaign to urge women to ask their doctors where their Pap smears are analyzed. At the very least, women should be told that their Pap tests may fail to detect abnormalities, many health experts say. This way, women may be less likely to skip their next gynecologic exam.

FAILURE RATE

The American College of Obstetricians and Gynecologists, citing studies of hundreds of woman, puts the Pap test's "false-negative" rate—the failure to reveal or report abnormalities—20% to 40%.

The Pap test's reliability compares unfavorably with that of other lab tests. Drug tests, for example, have been criticized as being inaccurate. But labs measured in a nationwide proficiency test last year had a much lower false-negative rate of about 5%. Even under the best of circumstances, says Dr. Anderson of Vancouver, a Pap test will have a false-negative rate of at least 10%.

To help bring error rates down, San Francisco's Dr. King argues for better pay and working conditions for cytotechs. "The field has become unattractive to intelligent, dedicated people of the kind we have always had," she says.

Above all, people in the field don't want Pap testing to remain laboratory medicine's errant stepchild. They prefer to think of it as a test so important that a commemorative stamp was issued in its name in 1978. At the White House ceremony marking the event, Postmaster General William Bolger said of Dr. Papanicolaou: "He wanted to eradicate those awful words so many doctors have quietly voiced: 'If we only had known sooner.' "

Mrs. Gray, the North Carolina woman who got a negative Pap-test report before finding she had cervical cancer, felt the tragic sting of that lament. After the cancer had spread through her body, she underwent several operations, chemotherapy and radiation. As part of a lawsuit, Mrs. Gray gave a videotaped deposition from her sickbed, describing in detail the agony of her struggle for life. The deposition ended with her vow: "I made some plans to beat this thing."

Two months later, Cindy Gray died.

WOMEN MAY WANT TO ASK WHO'LL SCREEN A PAP TEST

Women concerned about Pap-test accuracy might consider asking their doctors questions such as these:

What is the name of the lab, and is it accredited by a professional group? (Accreditation offers no guarantee, but at least it means someone is looking over the lab's shoulder.)

What are workoad levels at the lab? Are screeners salaried or paid on a piecework basis?

Can I get a copy of the lab report? (Don't assume that if you don't hear from the doctor the test must have been negative. There are such things as mixups, oversights, and lost reports.)

Is the lab nearby? (If a doctor sends the specimen to a lab far away, he should have a good reason.)

[From the Wall Street Journal, Nov. 2, 1987]

IN OKLAHOMA, A DIFFERENT LAB TO SCREEN PAP TESTS MEANS VERY DIFFERENT RESULTS

(By Walt Bogdanich)

OKLAHOMA CITY, OKLA.—Legislators can attest that women in this state take cancer screening seriously. When lawmakers in the late 1980s voted not to finance a free Pap smear program, women protested at the capital with such vigor that the legislators backpedaled.

The women's victory, it turns out, may have been hollow. Intent on reducing the program's cost, the state health department in the mid-1986 stopped sending Pap smears to be analyzed by its longtime contractor and began awarding one-year contracts to the lowest bidder.

Now, Adeline Yerkes, a state health official, says it is possible that hundreds of Oklahoma women are walking around with undiagnosed precancerous conditions because of misreported Pap-test results. The low-bid lab reported far fewer "abnormals" than did its predecessor, Oklahoma Teaching Hospitals.

For years, "abnormals" consistently came in at 7% to 9% of the total Pap smears analyzed each year, including a 9% rate in the year ended in June 1986. In the following 12 months, the new contractor, Northwest Laboratories Inc. in Oklahoma City, reported only about 3.5% abnormals, says Mrs. Yerkes, the head of the state program.

The figures suggest that Oklahoma officials "have something to worry about," says Lawrence Bergner, a physician at the National Cancer Institute. "They should really examine it."

But whether the results are misdiagnoses or statistical glitches won't be known for some time, if ever. Four months after the contract ended, the state still hadn't re-screened any significant number of slides to determine their accuracy. Mrs. Yerkes says it can afford to rescreen only 250 of the nearly 100,000 Pap smears. And it is still searching for someone to rescreeen just these 250.

She hasn't alerted women to the possible misdiagnoses. Any missed abnormalities, she explains, will be caught when the women show up for their next exam, Mrs. Yerkes says there is no need for panic, because cervical cancer develops slowly.

The state concedes, however, that women may move and be unreachable, or may neglect their next appointment. In addition, there is evidence that cervical cancer in some women develops much faster than previously believed.

"I think it's disgusting," says Dana Dye, who teaches cytotechnology—the screening of cell specimens—at the University of Oklahoma Health Sciences Center. "If she has any doubt, she should let somebody go over those slides."

Northwest Laboratories, which declined to be interviewed, won the contract for the 12 months in question with a bid of 1.50 a slide. The bid form from Oklahoma Teaching Hospitals, the old contractor, was more than twice that.

But the state didn't follow up on who actually did the screening. Northwest, it turns out, was so understaffed that it farmed out some of the work. It loaded hundreds of Pap-smear slides into a car and drove them to a cut-rate laboratory in Texas.

Mrs. Yerkes says Northwest's staffing problems became apparent early in the contract, with some screeners carrying excessive workloads. That was soon corrected, she says. But the contract lab was late delivering results, and seemed to have high screener turnover. "The quality of the reading wasn't up to our standards," she says.

The state has contracted with a different lab for the 12 months that began July 1 and has written staffing safeguards into the contract, Mrs. Yerkes says. But when a reporter examined the contract on file in the state capital, the safeguards weren't there. "I don't know what happened," Mrs. Yerkes says.

She says she inspected the lab that holds the new contract, Jerry L. Puls M.D. Inc. in Tulsa. "I know they have an adequate staff," she says. "All Paps are being screened in Tulsa in his own lab."

However, this newspaper learned that many slides the state sent to a new contractor weren't being screeend in a laboratory at all but rather were taken home by unsupervised technicians. In violation of federal regulations for Medicare-certified labs. Dr. Puls was told of the discovery and now says he has stopped the practice.

Jack Painter, the manager of the anatomic pathology laboratory at Oklahoma Teaching Hospitals, says that previous screening programs cut the number of deaths from cervical cancer and that now he fears death rates may go back up. But, says Betty McClellan, a pathologist in his laboratory: "Unfortunately, I think it will take years before the mistakes, if any, become apparent."

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5769 21/1
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PATIENT NAME	PATIENT ID	ROOM NUMBER	AGE	SEX	PHYSICIAN
ASTOR/DAVID				M	SCHER

PAGE	REQUISITION NO.	ACCESSION NO.	ID. NO.	COLLECTION DATE & TIME	LOG-IN-DATE	REPORT DATE	& TIME
01	K0327615	016011963		15OCT85	16OCT85	23OCT85	0255

TESTS REQUESTED
TAY SACHS (HEXOSAMINIDASE A),

☒ COMPLETE REPORT
☐ PARTIAL REPORT

TEST	RESULTS OUT-OF-RANGE	RESULTS NORMAL	UNITS	EXPECTED VALUES

TAY SACHS (SERUM):
HEXOSAMINIDASE A, SERUM
*TEST PERFORMED AT KINGSBROOK JEWISH MEDICAL CENTER
ISAAC ALBERT RESEARCH INSTITUTE
RUTLAND ROAD AND EAST 49TH STREET
BROOKLYN, NEW YORK 11203
*THE RESULTS OF BLOOD TEST INDICATE PATIENT IS NON-CARRIER
FOR THE TAY-SACHS GENE.

END OF REPORT: ASTOR/DAVID

DOH STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12201

David Axelrod, M.D.
Commissioner
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Linda A. Randolph, M.D., Ph.D.
Director
WADSWORTH CENTER FOR
LABORATORIES AND
RESEARCH
Herbert W. Dickerman, M.D., Ph.D.
Director

January 25, 1988

Mr. David Astor
3917 47th Street
Sunnyside, New York 11104

Dear Mr. Astor:

We have completed our review of the laboratory error which occurred in the test performed on you for Hexosaminidase A, the procedure used to determine carrier status for Tay-Sachs disease.

The test was ordered by Dr. Scher on October 16, 1985 and referred to International Clinical Laboratories, Inc. in Syosset New York (ICL). ICL referred the test to Kingsbrook Jewish Medical Center (KJMC) which received it on October 18, 1985.

KJMC performed the test correctly, but in calculating the value for Hexosaminidase A, made an arithmetic error which was not detected by quality control procedures then in place. This resulted in a report which indicated that you were not a carrier. The error was not discovered until Dr. Peterson called.

Since that time, the KJMC laboratory has installed a computer system which will reduce the chance of error for the future. Additionally, the procedures now call for spot checking calculations as an additional quality control step. These procedures should prevent a repeat of the problem.

You have our sincere sympathy in this regrettable and preventable situation. Please do not hesitate to contact me at (518) 474-1152 if you have any questions.

Sincerely,

Mary Anne Gardineer
Laboratory Center Administrator

cc: CLEU
LIU

ADVICE (10/20/87)

DEAR ABBY

DEAR ABBY: My wife, Kathy, and I are both Jewish, so when she became pregnant in 1985, I took a simple blood test to determine if I was a carrier of Tay-Sachs — a hideous disease that predominantly strikes Jewish children. About one out of 30 Jewish adults is a Tay-Sachs carrier. If a carrier marries another carrier, there is a one out of four chance that their baby will develop Tay-Sachs.

I was tested at a local hospital and was told I was not a carrier, so since both parents must be carriers in order to produce a Tay-Sachs child, there was no reason for Kathy to be tested.

In June 1986, Kathy had a beautiful baby. We named her Abigail. She appeared to be a normal, happy baby, but when she didn't sit up or progress the way other babies her age did, we became concerned and consulted a specialist. His diagnosis: Tay-Sachs. We were devastated! Abby, our daughter will never crawl, walk or speak. Instead, she will go blind, become paralyzed, have seizures and die before she is 3, 4 or 5 years old.

How could this have happened when I was told I was not a carrier? Our specialist called the hospital and discovered that the lab technician had made a simple mathematical error! We later learned that the hospital's policy was to only "spot-check" their results. Meanwhile, we looked into suing the lab, but were advised by several prominent malpractice attorneys that in New York it is not possible to collect damages for "pain and suffering." We finally found a lawyer who agreed to take our case, but were told not to expect too much.

Abby, no amount of money can compensate for having to watch one's child slowly die, but we want to warn other prospective parents so this won't happen to them. No one should have to go through the hell we are presently going through. You may use my name.

— David Astor, Queens, N.Y.

DEAR MR. ASTOR: My heart goes out to you, Kathy and your precious daughter. Thank you for caring enough to write as a warning to others.

Readers, be aware that Tay-Sachs has occurred in non-Jewish babies, too — but the incidence is much lower. And in order to reduce the possibility of a laboratory error, the man and woman should be tested twice — preferably at different labs.

MANHATTAN CLOSEUP

New York Newsday, 1/11/88

Photo by Susan Farley

In their kitchen, David and Kathy Astor feed 18-month-old Abigail through a tube.

Faulty Genetic Test Leaves Couple With a Dying Baby

By Merle English

David Astor had never heard about Tay-Sachs disease, and his wife, Kathy, knew very little about it. So when she got pregnant about nine months after their marriage in January, 1985, the couple anticipated the birth of a healthy baby.

Their daughter, Abigail, was born on June 10 the following year.

"There was nothing unusual," David Astor, 33, a writer and editor for Editor & Publisher magazine in Manhattan, recalled in an interview. "We didn't suspect anything until Abigail was maybe six months old and wasn't developing the way normal babies do. She wasn't sitting up. She wasn't crawling. We thought at first she was a slow developer, and our pediatrician told us there wasn't anything to worry about."

But by the time Abigail was 10 months old, the Astors knew something was terribly wrong. "She still wasn't sitting up. Her neck seemed to droop. We really began to panic," Astor said.

A pediatric neurologist noticed red spots in Abigail's eyes and diagnosed Tay-Sachs, a fatal neurological disease that affects mostly children born to couples of an Ashkenazi (Eastern European) Jewish background who carry the genes for the disease. One in every 30 people of that background does.

The Astors soon learned their baby is doomed to die within three years, and she is dying a slow death.

As she deteriorates before their eyes, they have become increasingly traumatized and angry. And they blame Kingsbrook Jewish Medical Center in Brooklyn for their distress. Astor said he was tested at the hospital and told erroneously that he was not a carrier of the Tay-Sachs gene. The error has triggered a state investigation of the hospital.

A month after his wife became pregnant, Astor was tested for the gene, on the recommendation of her obstetrician, but she was not. "I called up and found out it [the test] was negative, so I didn't think any more of it, because for a kid to have Tay-Sachs, both parents have to be carriers," he said. But as Abigail's deterioration worsened, further tests confirmed the disease and that Kathy Astor, as well as her husband, was a carrier.

"We were just devastated," David Astor said. "You think you have a healthy baby one day and the next you are told your baby has a 100 per cent chance of dying. There is no hope. Abigail is our first kid, and like most parents we really were thrilled with her."

Harold Harris, a spokesman for Kingsbrook, said that under state law, the hospital cannot "discuss and release information regarding . . . an individual's medical condition or treatment."

The Astors, who live in Sunnyside, Queens, said they are most angry because of the way the hospital has treated them. "We thought Kingsbrook would call and apologize to us. They never did," David Astor said. "We wrote them and we haven't had a reply. No offer of help. No apology."

Helplessly, they watch Abigail's decline. "She progressively lost her sight," David Astor said. "She's 95 per cent paralyzed. She has lost the ability to swallow, so we feed her by tube now. She can't roll over. She can't cry."

The experience is a drain on their emotions. Kathy Astor wants to have another child, but has had three miscarriages. "I'm 37, and it's very anxiety-provoking," she said. "I'm worried that I will never get pregnant again. It's the worst thing that ever happened to me." The couple are undergoing therapy to hold their marriage together and to help them cope with "the grief, the anguish and the fact that were going to have to lose our daughter, that this could have been prevented," Kathy Astor said.

It has also affected their finances and Kathy Astor's career. The Astors have had to provide nurses full-time to care for Abigail. And because of the strain, Kathy Astor had to take less stressful work than her $26,000-a-year job as a copy editor and proofreader for a Manhattan book publisher, taking a $5,000 cut in salary.

The couple wants to take legal action against the hospital, but David Astor said that under state law although they can recover medical expenses not covered by insurance, they can't sue for pain and suffering.

Dr. Lee Goldsmith, a medical attorney, said there might be a cause of action for pain and suffering based on the couple's emotional distress from watching their child die.

Bill Fagel, a spokesman for the state Health Department, said that the hospital has "had a pretty decent record" but that "if it's true that they didn't do the test correctly or were at fault," the hospital could be cited for deficiency and would be given a chance to file a plan of correction.